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Characterising the patient experience of diagnostic lumbar puncture in idiopathic intracranial hypertension; a cross-sectional online survey.

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Title: Characterising the patient experience of diagnostic lumbar puncture in idiopathic intracranial hypertension; a cross-sectional online survey.

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53 53 **Alexandra J. Sinclair:** Conception and design of the survey; interpretation of the results and critical review of the manuscript54
55 5456
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5 **Abstract**6
7
8 **Objectives**9
10 Patients with idiopathic intracranial hypertension (IIH) usually require multiple lumbar
11 punctures during the course of their disease, and often report significant morbidity
12 associated with the procedure. The aim of this study was to assess the patient's experience
13 of diagnostic lumbar puncture (LP) in IIH.
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16
1718 **Design, methods and participants**19
20
21 A cross-sectional study of IIH patients was conducted using an online survey, with the
22 questions designed in collaboration with IIH:UK (the UK IIH charity). Responses were
23 collated over a two-month period from April to May 2015.
24
25
2627 **Results**28
29
30 502 patients responded to the survey, of which 463 were analysed for this study. 40% of
31 patients described severe pain during the LP (VRS ≥ 8), and the median pain score during
32 the LP was 7 (VRS, IQR 5-7). The majority of patients felt they received insufficient pain
33 relief (85%). Levels of anxiety about future LP's were high (median VRS 7, IQR 4-10), with
34 47% being extremely anxious (VRS ≥ 8). LPs performed as an emergency were associated
35 with significantly greater pain scores compared to elective procedures (median 7, IQR 5-7
36 vs. 6, IQR 4-8, $p=0.012$). Higher LP pain scores (VRS) were significantly associated with
37 poorly informed patients (Spearman correlation, $r=-0.32$, $p<0.001$). Patients felt more
38 informed when the LP was performed by Specialist Registrar compared to a Junior Doctor
39 (median 7 vs. 5, $p=0.001$) or Consultant compared to Junior Doctor (median 8 vs. 5,
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50 $p<0.001$).
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81 Conclusions

82 This study was commissioned by the IIH patient group and is the first to document the
83 patient experience of diagnostic lumbar punctures in IIH. It shows that the majority of these
84 patients are experiencing significant morbidity from pain and anxiety. Additionally, patient
85 experience of LP may be improved through enhanced pre-procedural information, and where
86 possible, avoiding emergency LP's in favour of LP's booked on an elective day case unit.

87

Strengths and limitations of this study

- This large sample size UK survey is the first known to directly and specifically document the patient experience of diagnostic lumbar punctures in IIH, and confirms that a significant number of these patients are experiencing morbidity from pain and anxiety related to the procedure.
- The use of an online questionnaire ensured anonymity, thus increasing the likelihood of honest reporting by patients of their subjective experiences of the procedure.
- Given the retrospective nature of this study, the results may be susceptible to recall bias, thus limiting the generalisability of our findings.
- The study suggests practical recommendations for areas in which we can intervene to improve the patients' experience of diagnostic LP in IIH.

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96 Introduction

97 Idiopathic intracranial hypertension (IIH) is characterised by raised intracranial pressure
98 (ICP) which can cause papilloedema with significant visual loss in some, as well as severe
99 disabling headaches which significantly impact on quality of life in the majority (1)(2). The
100 diagnostic criteria for IIH is based on an elevated lumbar puncture (LP) opening pressure
101 (≥ 250 mm CSF in adults) in a properly performed lumbar puncture (3).

102 Many patients have multiple LPs during the disease course typically to assess disease
103 severity, and in some cases as a therapeutic strategy. Established complications of LPs
104 include local discomfort, low pressure headaches and more rarely infection or local
105 haemorrhage (4). We have been made aware of an additional significant complication of LPs
106 voiced by the patients themselves. The patients describe a very negative experience of LP's
107 associated with anxiety, fear and pain during and after the procedure. The National charity
108 IIH:UK (Registered Charity in England and Wales no 1143522 & Scotland SCO43294)
109 approached us with concerns about the IIH patient experience of LP's. Patient experience of
110 spinal anaesthesia and LP has previously been studied (5)(6). However, the experience of
111 IIH patients undergoing LP has not been evaluated. LP's are typically more technically
112 challenging in the IIH population as over 90% of these patients are obese (3).

113 The aim of this study was to assess the patient's experience of diagnostic LPs in IIH. We
114 aimed disseminate this evidence to medical professionals to increase awareness of this
115 potential morbidity of LP in IIH patients. Furthermore, we aimed to use evidence from this
116 study as a catalyst to drive improvements in patient care.

117 Material and Methods

118 The study was carried out in collaboration with IIH:UK who canvassed their members
119 through the charity's contact network to establish the initial interest in the subject area.
120 IIH:UK established the question topics and contacted our clinical team to provide guidance

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2
3 121 on how to frame quantitative questions. A cross-sectional study was then conducted using
4
5 122 an online survey. IIH:UK sent a survey monkey questionnaire through social media outlets
6
7 123 (Facebook, Twitter (@IIHUK) and IIH:UK charity website (www.IIHUK.org), and allowed a
8
9 124 two-month period from 1st April to 31st May 2015 for responses. Questionnaires were
10
11 125 excluded if the respondents were under the age of 16 years or the survey was incomplete
12
13 126 (missing key data fields) or uninterpretable. Anonymised data was analysed by the clinical
14
15 127 team with input from the clinical research facility statistician (PN).

16
17 128 The questionnaire (see supplementary document) detailed baseline demographic details
18
19 129 (age, weight and height), and details of the LP (emergency versus planned procedure,
20
21 130 hospital setting, number of attempts, whether went on to have an X-Ray guided procedure
22
23 131 and seniority of doctor performing). Data on anxiety (for the LP and future LP's), pain
24
25 132 experienced and extent of understanding of the procedure was also collected. Patients were
26
27 133 asked to quantify responses using a verbal rating score (VRS) 0-10 with 0 being the
28
29 134 minimum and 10 the maximum score.

30 31 135 **Statistical analysis**

32
33 136 Statistical analysis was performed using SPSS versions 24 (SPSS Inc., Chicago, IL,
34
35 137 USA) and GraphPad Prism 7 for Windows (GraphPad Software Inc., La Jolla, CA, USA).
36
37 138 Assessment of data for normality was performed for each analysis. Normally distributed data
38
39 139 was reported using mean and standard deviation (SD), and non-normally distributed data
40
41 140 was reported using median and interquartile range (IQR). For all comparisons of continuous
42
43 141 variables, a non-parametric test was used due to non-normality of data distribution. For
44
45 142 comparison of two medians Mann-Whitney U tests were used, whilst for comparison of
46
47 143 multiple medians Kruskal-Wallis H tests were used. Spearman's rank-order correlation was
48
49 144 used to analyse the correlation between how informed the patients were and how much pain
50
51 145 they felt. For comparison of categorical variables Chi square tests were used. Values were
52
53 146 considered statistically significant when P values were less than 0.05.
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147 **Results**

148 **Demographics**

149 There were 502 responders to the study, of which 463 were eligible for analysis. 18
150 responders did not complete the survey, 11 were under the age of 16 years, and 10 gave
151 incomplete answers or ambiguous information that could not be objectively interpreted
152 (Figure 1). The mean age was 33 years (SD 8.9), 98.5% were female (n=456), with a mean
153 weight of 97.4kg (SD 22.3), and a mean Body Mass Index (BMI) of 36 kg/m² (SD 8.3). The
154 median number of LPs undergone since diagnosis was 4 (inter-quartile range [IQR] 1-11),
155 though 3.1% of patients (n=15) reported more than 50 LPs. When number of LPs was
156 adjusted to reflect length of disease, the median number of LPs per year since diagnosis
157 was 1.3 (IQR 0.3-3.6) (Table 1).

158 **Pain, Anxiety & Analgesia**

159 The majority of patients indicated they were extremely scared about the imminent LP
160 (median VRS 8, IQR 6-10), with 60% indicating a VRS ≥8 in relation to how scared they felt
161 (Figure 2A & 2B). 40% of patients described severe pain during the LP (VRS ≥8) with a
162 median pain score of 7 (VRS, IQR 5-8) (Figure 2A & 2B). Additionally, the majority of
163 patients felt they received insufficient pain relief (85%). Levels of anxiety about future LP's
164 were high (median VRS 7, IQR 4-10), with 47% being extremely anxious (VRS ≥8) (Figure
165 2A & 2D). There was no relationship found between the pre-procedure anxiety levels and the
166 subsequent recalled pain score of the LP.

167 **Setting of LP and pre-procedural information**

168 LPs were predominantly performed in the emergency setting (72%), as opposed to as an
169 elective planned procedure on day-case unit. Importantly the LPs performed as an
170 emergency were associated with significantly greater pain scores compared to elective
171 procedures (VRS median 7, IQR 5-7 vs 6, IQR 4-8 respectively, p=0.012).

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3 172 Only 37% of patients felt well informed about LP pre-procedure (VRS ≥ 8); 27% felt poorly
4 informed (VRS 0-3), and 7% did not feel they were informed at all (VRS 0). Higher LP pain
5 173 scores (VRS) were significantly associated with patients being poorly informed (Spearman
6 174 correlation, $r=-0.32$, $p<0.001$) (Figure 3B). Patients felt better informed if they had an elective
7 175 planned LP compared to an emergency procedure (median 7, IQR 5-10 versus median 6,
8 176 IQR 5-10, $p=0.011$).
9 177

15 178 **Difficulty of LP and need for X-ray guided procedure**

17 179 47% of patients had 2 or more doctors attempt their LP (median 1, IQR 1-2) while 45%
18 180 had greater than 3 attempts (number of times needle inserted) before success (median 1,
19 181 IQR 1-4). 10.7% went on to have an X-Ray guided procedure due to failure of the initial LP,
20 182 and the BMI was significantly higher in this group (mean kg/m^2 40.3 vs. 35.5, $p=0.001$)
21 183 (Figure 3A). Compared to those that had normal LPs, the patients having X-Ray guided
22 184 procedures felt less informed (VRS median 3 vs 6, $p=0.002$), suffered more pain (VRS
23 185 median 8 vs 7, $p=0.004$), and were more anxious about future LPs (VRS median 9 vs 7,
24 186 $p=0.003$).
25 187

34 187 **Grade of Doctor performing LP**

36 188 Patients felt more informed when the LP was performed by a Specialist Registrar (SpR)
37 189 compared to a Junior doctor (median VRS 7 vs 5, $p=0.001$) or Consultant compared to a
38 190 Junior doctor (median VRS 8 vs 5, $p<0.001$), though there was no significant difference in
39 191 the pain scores reported. They also suffered from less severe post-LP headaches (SpR vs
40 192 Junior median VRS 7 vs 8, $p<0.001$, Consultant vs Junior median VRS 6.5 vs 8, $p=0.003$),
41 193 and length of post-LP headache (SpR vs Junior median days 3 vs 6, $p=0.02$, Consultant vs
42 194 Junior median days 4 vs 6, $p=0.9$).
43 195

51 195 **Discussion**

53 196 This is the first study, to the best of our knowledge, to document the patient experience
54 197 of diagnostic lumbar punctures in IIH. It has shown that a number of patients are recalling
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198 significant pain and anxiety. This morbidity is associated with inadequate pre-procedural
199 information, the environment the LP is performed in (emergency setting being associated
200 with increased pain), and the seniority of the doctor performing the LP.

201 Anaesthetists have long recognised the importance of the patient experience of spinal
202 anaesthesia as an outcome measure and an indicator of quality of care (5) (6) (7). This is
203 reflected in the high satisfaction levels patients report with the procedure (96-97%), which is
204 in stark contrast to the feedback here. The differences between the anaesthetic population
205 and the IIH patient group may be related to the procedure being technically challenging due
206 to the patient's high BMI, the procedure happening as an emergency and in some having
207 multiple LPs during the course of their IIH. It may also be due to anaesthetists having better
208 technical skills due to performing the procedure more often, in addition to more closely
209 supervised and rigorous training

210 This was a large sample size study (463 responders) where patients could respond
211 anonymously, thus increasing the likelihood of honest reporting of their subjective
212 experiences of the procedure. This cohort reports the LP experience as negative with 40% of
213 patients experiencing severe pain (VRS ≥ 8) during the procedure, 85% saying they did not
214 receive adequate analgesia and 47% stating they were extremely anxious (VRS ≥ 8) about
215 future LPs.

216 The majority of the group did not feel they received adequate pre-procedural information,
217 with 63% not feeling well informed (VRS < 8), and 7% saying that they were not informed at
218 all (VRS =0). Patient who were less informed experienced more pain during the procedure.
219 This highlights a key area where simple steps (see Box 1) could be made which may
220 improve patient care.

221 Environment also had a bearing on the patient experience with 72% of LPs being
222 performed in the emergency setting; this was associated with the patient feeling less
223 informed, and reporting significantly higher pain scores, compared to an elective procedure
224 on a day-case unit. Optimisation of the environment for the patient undergoing LP could
225 therefore positively affect their outcome (see Box 1). The day case environment may provide

226 access to doctors adequately trained in performing LPs as well as a less time-pressurised
227 environment. Time to reflect on the procedure, read pre-procedural information and give
228 informed consent may help improve the overall experience. Although diverting IIH patients
229 away from the emergency room would likely benefit the majority, it may not be practical for a
230 minority of papilloedema cases where there is progressive or rapid loss of visual function,
231 and the need for acute diagnosis.

232 The study also suggests that there is also scope for improving our technical skills in LP,
233 as 85% of our cohort stated that they did not receive adequate analgesia, with 45%
234 undergoing greater than 3 attempts (defined as the needle being fully withdrawn between
235 attempts), and 47% having 2 or more doctors attempt the LP. When the LP was performed
236 by a doctor more junior than registrar (30% of the time), the patients felt less informed, and
237 reported more severe and longer lasting post-LP headaches. We acknowledge that the grade
238 of doctor performing the LP may not be accurately recalled by the patient and maybe more
239 of a reflection of the patient's confidence in the doctor. However, diverting LPs into the day-
240 case setting would provide an opportunity where the junior doctors could be appropriately
241 supervised and trained, which has been shown to increase their ability to perform the
242 procedure (8).

243 In this cohort, 10.7% of patients reported having an x-ray guided procedure due to failure
244 of the initial LP, with the BMI being significantly higher in this group (mean 40.3kg/m² vs.
245 35.5kg/m², p=0.001). This finding is in keeping with a recent study which showed a strong
246 correlation between BMI and procedure failure, with half of the failed LP's occurring in
247 patients with a BMI greater than 35kg/m² (9). The inability to palpate landmarks in obese
248 patients is likely to be a significant driver of this correlation (10). The x-ray guided LP group
249 felt less informed, reported more pain, and were more likely to feel anxious about future LPs;
250 findings most likely due to the number of failed attempts before the x-ray guided procedure.
251 The growing evidence base for use of ultrasound guidance, particularly in patients with a
252 higher BMI and absence of landmarks (11), suggests that its use in the IIH patient cohort

253 may increase the success rate of the initial LP and decrease the number that require x-ray
254 guided procedures (see Box 1).

255 For clinical care a positive experience of a diagnostic LP will positively impact on the
256 patient's future engagement with healthcare services, whilst in IIH research LP experience
257 affects recruitment to clinical trials (12); it is therefore critical that clinicians optimise patient
258 care.

259 **Limitations**

260 The main limitation of the study is its retrospective nature and as such the results are
261 likely susceptible to recall bias. Interpretation of some of the study questions is problematic:
262 for example, for questions such as the number of attempts for a lumbar puncture and the
263 seniority of the doctor performing the procedure, the respondents may not accurately know
264 the answer.

265 **Conclusion**

266 There has been a growing consensus in recent years that if healthcare services are to
267 better deliver patient-centred care then research needs to be more reflective of patients'
268 needs and concerns (13)(14). This study was commissioned by the IIH patient group and is
269 the first to document the patient experience of diagnostic lumbar punctures in IIH. It
270 documents experiences of significant pain and anxiety associated with both inadequate pre-
271 procedural information and the setting the LP is performed in. The study suggests a number
272 of practical steps that may improve the patient experience of LP's.

273

Recommendations for improving patient experience of diagnostic LP in IIH

- Providing enhanced pre-procedural information.
- Where possible, diverting emergency department LPs to elective procedures on dedicated day case units.

- Simulation training for doctors and specialist nurses to develop appropriate technical (including ultrasound guidance) and human factor skills (such as communication, empathy and leadership) for performing LPs in a technically difficult patient cohort.
- Implementing widespread patient reported outcome measures for LP's to guide the need for service improvements and training needs.

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310 **Competing interests statement**

311 None Declared.
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313 **Author's contribution to the research**

314 **William J. Scotton** Compilation of the survey results; statistical analysis; interpretation of
315 the results and drafting the manuscript

316 **Susan P. Mollan** Conception and design of the survey; critical review of the manuscript

317 **Thomas Walters** Compilation of the survey results and statistical analysis

318 **Sandra Doughty** Conception and design of the survey

319 **Peter Nightingale** Statistical analysis

320 **Hannah Botfield** Statistical analysis and interpretation of the results

321 **Keira Markey**: Interpretation off the results and drafting of the manuscript

322 **Andreas Yiangou**: Interpretation off the results and drafting of the manuscript

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3 323 **Shelly Williamson** Conception and design of the survey

4 324 **Alexandra J. Sinclair** Conception and design of the survey; interpretation of the results and
5
6 critical review of the manuscript
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10 327 **All authors have read and approved the final manuscript.**

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19 331 **Tables**

20
21 332 **Table 1:** Baseline characteristics of eligible responders

Variable	No. (%) n=463
Age, mean, years (SD)	32.9 (8.9)
Female sex	456 (98.5%)
Weight, mean, kg (SD)	97.2 (22.5)
BMI, mean (SD)	36.0 (8.3)
LPs since diagnosis, median (IQR)	4 (1-11)
LPs per year since diagnosis, median (IQR)	1 (1-4)

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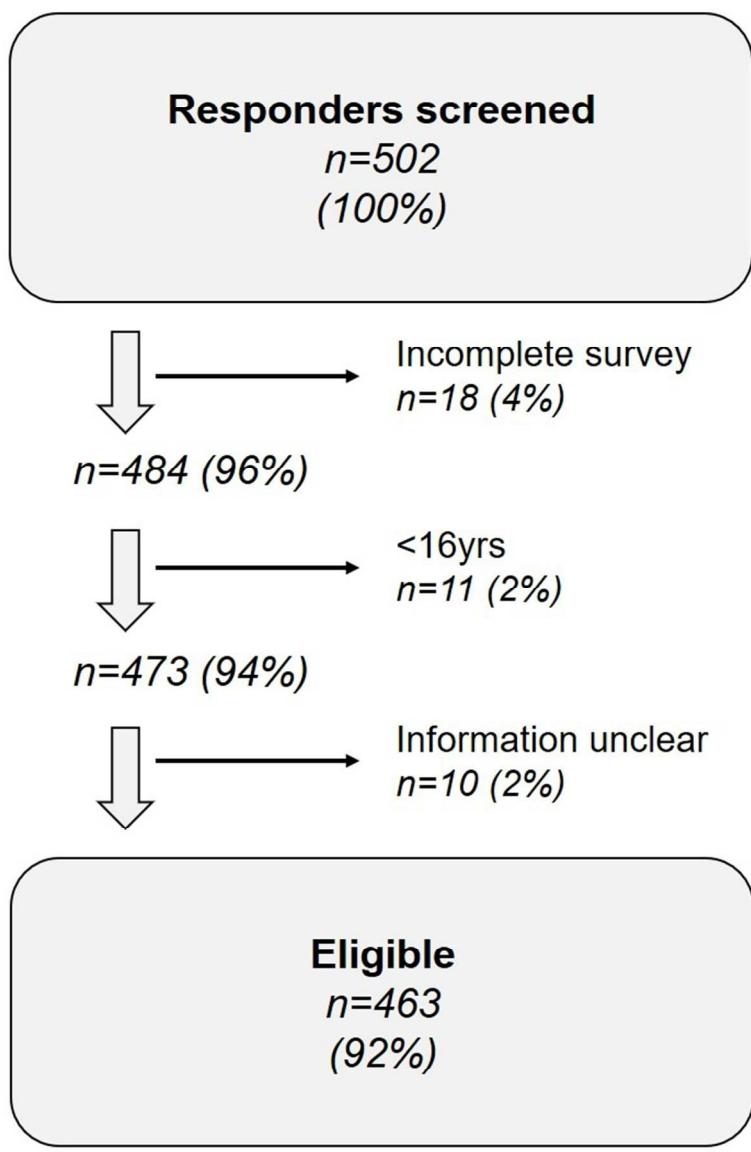


Table 1: Baseline characteristics of eligible responders
209x289mm (96 x 96 DPI)

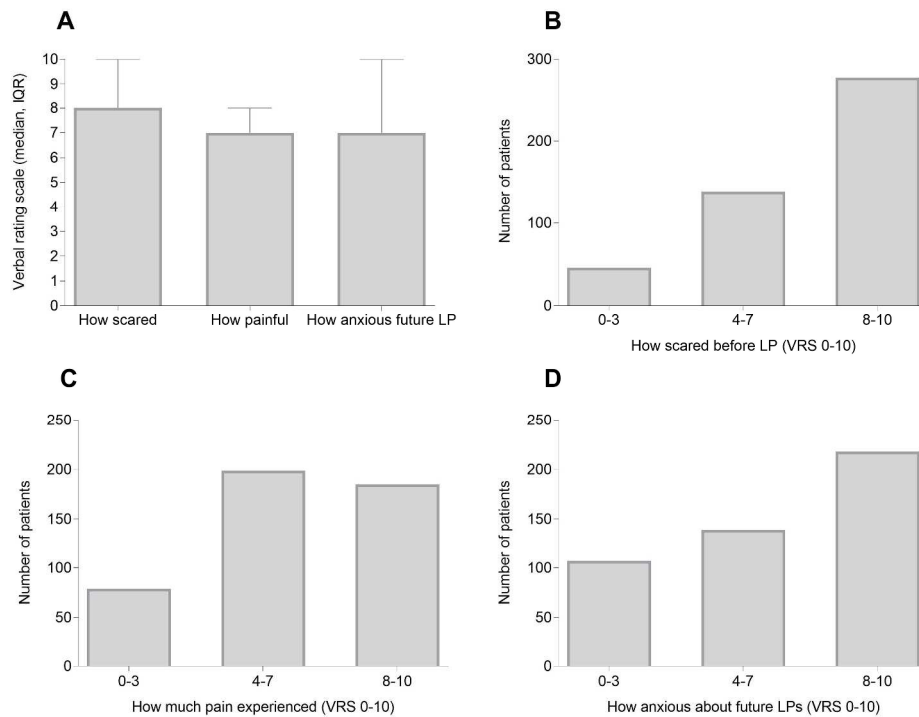


Figure 2: Patients' expectations and experience of LP. (A) Median VRS (0-10, IQR) for how scared patient was before LP, how painful the LP was and how anxious they were about future LPs. (B) Number of patients that were mildly (0-3), moderately (4-7), or very scared (8-10) before having an LP. (C) Number of patients that experienced mild (VRS 0-3), moderate (VRS 4-7) or severe (VRS 8-10) pain during the LP. (D) Number of patients that were mildly (VRS 0-3), moderately (VRS 4-7) or very anxious (VRS 8-10) about future LPs. [VRS 0=minimum and 10=maximal score]

284x212mm (300 x 300 DPI)

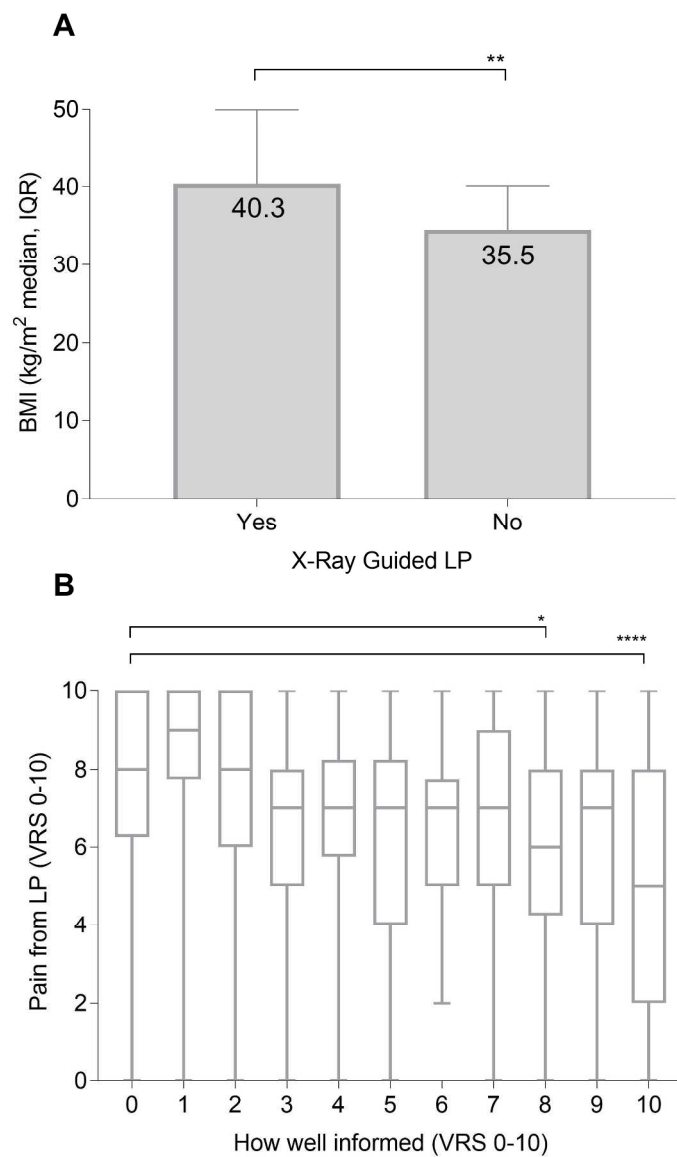


Figure 3: X-Ray guided LPs and relationship of pre-procedural information to patient experience. (A) BMI (median, IQR) and association with whether patient had X-Ray guided LP. (B) Association between how well-informed patient was before LP, and how painful LP was (median VRS, IQR, min-max). ns $p > 0.05$, * $p \leq 0.05$, ** $p \leq 0.01$, **** $p \leq 0.001$. [VRS 0=minimum and 10=maximal score]

182x275mm (300 x 300 DPI)

IHHUK Online Questionnaire

Demographics

1. How old were you at time of diagnostic LP?
2. What was date of your first lumbar puncture? (Do not worry if you cannot remember the exact day, but please specify month and year)
3. Since your first diagnostic LP, how many LPs have you had? (Please approximate if not sure of the exact number)
4. What is your height (metres)?
5. What is your weight (kg)?

Details of lumbar puncture

1. Was your first admission regarding your LP planned (you were sent an appointment by your doctor) or as an emergency?
2. Where in the hospital did the first LP take place? (Emergency department, Ward or In Theatre)
3. How many different doctors attempted your diagnosing LP? (i.e how many different doctors tried inserting a needle)
4. How many attempts were made to get a diagnostic LP? (An attempt being defined as a needle being inserted)
5. If the initial LP failed to get a reading did you go on to have it done in theatre under X-ray guidance?

Patient experience of lumbar puncture

1. How frightened were you about the thought of the LP before the procedure on a scale 0-10? (0 being not frightened at all, 10 being the most scared you've ever felt)
2. How well do you feel you were informed about the procedure prior to the LP on a scale 0-10? (0 being not informed, 10 being fully informed)
3. Was adequate analgesia (i.e. local anaesthetic) used in your diagnosing LP?

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4. How much pain did you experience during the LP on a scale of 0-10? (0 being pain free, 10 being worst pain ever experienced)
5. On a scale of 0-10, how anxious do you feel about having LPs in the future? (0 being not anxious, 10 being the most anxious you've ever felt)

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (Pg1) (b) Provide in the abstract an informative and balanced summary of what was done and what was found (Pg 3-4)
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported (Pg5)
Objectives	3	State specific objectives, including any prespecified hypotheses (Pg5)
Methods		
Study design	4	Present key elements of study design early in the paper (Pg5-6)
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection (Pg6)
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants (Pg6 & Figure 1) (b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable (Pg5-6)
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group (Pg5-6)
Bias	9	Describe any efforts to address potential sources of bias (Pg11)
Study size	10	Explain how the study size was arrived at (Pg6)
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why (Pg 6)
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (Pg6) (b) Describe any methods used to examine subgroups and interactions (Pg6) (c) Explain how missing data were addressed (Pg6 – responders with missing data excluded from study) (d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy (n/a) (e) Describe any sensitivity analyses (n/a)

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Results

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (Pg 7 & Figure 1) (b) Give reasons for non-participation at each stage (see above) (c) Consider use of a flow diagram (Figure 1)
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (Pg 7 & Table 1) (b) Indicate number of participants with missing data for each variable of interest (Pg 7) (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures (Pg7-8)
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (Pg7-8) (b) Report category boundaries when continuous variables were categorized (Pg7-8) (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period (n/a)
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses (n/a)

Discussion

Key results	18	Summarise key results with reference to study objectives (Pg 8-10)
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias (Pg11)
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence (Pg11)
Generalisability	21	Discuss the generalisability (external validity) of the study results (Pg9)

Other information

Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based (Pg2)
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*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Negative patient experience of lumbar puncture in Idiopathic Intracranial Hypertension: a cross-sectional online survey.

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SCHOLARONE™
Manuscripts

1 **Title:** Negative patient experience of lumbar puncture in Idiopathic Intracranial
2 Hypertension: a cross-sectional online survey.

3
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13
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15
16 35 interpretation of statistical analysis, and to the IIH UK as well as the IIH patient group without
17
18 36 which this study would not have been possible
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21 37

22 38 **Competing interests statement**

23
24 39 None Declared.
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27 40

28 41 **Author's contribution to the research**

29
30 42 **William J. Scotton:** Compilation of the survey results; statistical analysis; interpretation of the results and drafting the
31
32 43 manuscript

33 44 **Susan P. Mollan:** Conception and design of the survey; critical review of the manuscript

34 45 **Thomas Walters:** Compilation of the survey results and statistical analysis

35 46 **Sandra Doughty:** Conception and design of the survey

36 47 **Hannah Botfield** Statistical analysis and interpretation of the results

37 48 **Keira Markey:** Interpretation off the results and drafting of the manuscript

38 49 **Andreas Yiangou:** Interpretation off the results and drafting of the manuscript

39 50 **Shelly Williamson:** Conception and design of the survey

40 51 **Alexandra J. Sinclair:** Conception and design of the survey; interpretation of the results and critical review of the manuscript
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46 53 **All authors have read and approved the final manuscript.**

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48 54 **Data sharing statement:** We are happy to share all data, including raw data if requested
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50
51 55

Abstract**Objectives**

Patients with idiopathic intracranial hypertension (IIH) usually require multiple lumbar punctures during the course of their disease, and often report significant morbidity associated with the procedure. The aim of this study was to assess the patient's experience of diagnostic lumbar puncture (LP) in IIH.

Design, methods and participants

A cross-sectional study of IIH patients was conducted using an anonymous online survey, with the questions designed in collaboration with IIH UK (the UK IIH charity). Responses were collated over a two-month period from April to May 2015. Patients were asked to quantify responses using a verbal rating score (VRS) 0-10 with 0 being the minimum and 10 the maximum score.

Results

502 patients responded to the survey, of which 463 were analysed for this study. 40% of patients described severe pain during the LP (VRS ≥ 8), and the median pain score during the LP was 7 (VRS, IQR 5-7). The majority of patients felt they received insufficient pain relief (85%). Levels of anxiety about future LPs were high (median VRS 7, IQR 4-10), with 47% being extremely anxious (VRS ≥ 8). LPs performed as an emergency were associated with significantly greater pain scores compared to elective procedures (median 7, IQR 5-7 vs. 6, IQR 4-8, $p=0.012$). 10.7% went on to have an X-Ray guided procedure due to failure of the initial LP, and the BMI was significantly higher in this group (mean kg/m^2 40.3 vs. 35.5, $p=0.001$). Higher LP pain scores (VRS) were significantly associated with poorly informed patients (Spearman correlation, $r=-0.32$, $p<0.001$). Patients felt more informed when the LP was performed by Specialist Registrar compared to a Junior Doctor (median 7 vs. 5, $p=0.001$) or Consultant compared to Junior Doctor (median 8 vs. 5, $p<0.001$).

81 Conclusions

82 This study was commissioned by the IIH patient group and is the first to document the
83 patient experience of diagnostic lumbar punctures in IIH. It shows that the majority of these
84 patients are experiencing significant morbidity from pain and anxiety. Patient experience of
85 LP may be improved through changing clinical practice to include universal detailed pre-
86 procedural information, and where possible, avoiding emergency LPs in favour of LP's
87 booked on an elective day case unit (Box 1).

88

Box 1: Strengths and limitations of this study

- This large sample size UK survey is the first known to directly and specifically document the patient experience of diagnostic lumbar punctures in IIH, and confirms that a significant number of these patients are experiencing morbidity from pain and anxiety related to the procedure.
- The use of an online questionnaire ensured anonymity, thus increasing the likelihood of honest reporting by patients of their subjective experiences of the procedure.
- Given the retrospective nature of this study, the results may be susceptible to recall bias, thus limiting the generalisability of our findings.
- The study suggests practical recommendations for areas in which we can intervene to improve the patients' experience of diagnostic LP in IIH.

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91 Introduction

92 Idiopathic intracranial hypertension (IIH) is characterised by raised intracranial pressure
93 (ICP) which can cause papilloedema with significant visual loss in some, as well as severe
94 disabling headaches which significantly impact on quality of life in the majority (1)(2). The
95 diagnostic criteria for IIH is based on an elevated lumbar puncture (LP) opening pressure
96 (≥ 250 mm CSF in adults) in a properly performed lumbar puncture (3).

97 Many patients have multiple LPs during the disease course typically to assess disease
98 severity, and in some cases as a therapeutic strategy. Established complications of LPs
99 include local discomfort, low pressure headaches and more rarely infection or local
100 haemorrhage (4). We have been made aware of an additional significant complication of LPs
101 voiced by the patients themselves. The patients describe a very negative experience of LP's
102 associated with anxiety, fear and pain during and after the procedure. The National charity
103 IIH:UK (Registered Charity in England and Wales no 1143522 & Scotland SCO43294)
104 approached us with concerns about the IIH patient experience of LP's. Patient experience of
105 spinal anaesthesia and LP has previously been studied (5)(6). However, the experience of
106 IIH patients undergoing LP has not been evaluated. LP's are typically more technically
107 challenging in the IIH population as over 90% of these patients are obese (3).

108 The aim of this study was to assess the patient's experience of diagnostic LPs in IIH. We
109 aimed disseminate this evidence to medical professionals to increase awareness of this
110 potential morbidity of LP in IIH patients. Furthermore, we aimed to use evidence from this
111 study as a catalyst to drive improvements in patient care.

112 Material and Methods

113 Public and Patient Involvement

114 This research was initiated, designed and conducted by IIH UK, a charity who supports
115 IIH patients and carers. The charity agreed at a Trustee meeting to design a survey to
116 investigate the magnitude of lumbar puncture related anxiety in response to their
117 overwhelming messages from patients. When the first survey was performed, the Trustees

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3 118 recognised that they would need help in analysis of the data and ask addition questions so a
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5 119 further survey was conducted. The clinical researchers at the University Hospitals
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7 120 Birmingham provided support with statistical analysis and critical review of the data.

8
9 121 Dissemination of the results was planned via physician and patient meetings, through
10
11 122 medical and patient lead social media, and on the IIH UK patients' charity website.

123 **Study Design**

124 The cross-sectional study was conducted using an online survey. IIH UK sent a survey
125 monkey questionnaire through social media outlets (Facebook, Twitter (@IIHUK) and IIH UK
126 charity website (www.IIHUK.org), and allowed a two-month period from 1st April to 31st May
127 2015 for responses. Questionnaires were excluded if the respondents were under the age of
128 16 years or the survey was incomplete (missing key data fields) or uninterpretable.
129 Anonymised data was analysed by the clinical team with input from the clinical research
130 facility statistician (PN). As the charity board had already agreed with their members
131 beforehand, and both surveys instructed the respondents that the information would be used
132 to be published within the medical literature, no further ethical approval was required.

133 The questionnaire (see supplementary document) detailed baseline demographic details
134 (age, weight and height), and details of the LP (emergency versus planned procedure,
135 hospital setting, number of attempts, whether went on to have an X-Ray guided procedure
136 and seniority of doctor performing). Data on anxiety (for the LP and future LP's), pain
137 experienced and extent of understanding of the procedure was also collected. Patients were
138 asked to quantify responses using a verbal rating score (VRS) 0-10 with 0 being the
139 minimum and 10 the maximum score.

140 **Statistical analysis**

141 Statistical analysis was performed using SPSS versions 24 (SPSS Inc., Chicago, IL,
142 USA) and GraphPad Prism 7 for Windows (GraphPad Software Inc., La Jolla, CA, USA).
143 Assessment of data for normality was performed for each analysis. Normally distributed data
144 was reported using mean and standard deviation (SD), and non-normally distributed data

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3 145 was reported using median and interquartile range (IQR). For all comparisons of continuous
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5 146 variables, a non-parametric test was used due to non-normality of data distribution. For
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7 147 comparison of two medians Mann-Whitney U tests were used, whilst for comparison of
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9 148 multiple medians Kruskal-Wallis H tests were used. Spearman's rank-order correlation was
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11 149 used to analyse the correlation between how informed the patients were and how much pain
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13 150 they felt, as well as between BMI and how scared a patient was beforehand, how much pain
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15 151 they felt, and how anxious they felt about future LPs. For comparison of categorical variables
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17 152 Chi square tests were used. Values were considered statistically significant when P values
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19 153 were less than 0.05.

20 21 154 **Results**

22 23 155 **Demographics**

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26 156 There were 502 responders to the study, of which 463 were eligible for analysis. 18
27
28 157 responders did not complete the survey, 11 were under the age of 16 years, and 10 gave
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30 158 incomplete answers or ambiguous information that could not be objectively interpreted
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32 159 (Figure 1). The mean age was 33 years (SD 8.9), 98.5% were female (n=456), with a mean
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34 160 weight of 97.4kg (SD 22.3), and a mean Body Mass Index (BMI) of 36 kg/m² (SD 8.3). The
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36 161 median number of LPs undergone since diagnosis was 4 (inter-quartile range [IQR] 1-11),
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38 162 though 3.1% of patients (n=15) reported more than 50 LPs. When number of LPs was
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40 163 adjusted to reflect length of disease, the median number of LPs per year since diagnosis
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42 164 was 1.3 (IQR 0.3-3.6) (Table 1).

43 44 165 **Pain, Anxiety & Analgesia**

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47 166 The majority of patients indicated they were extremely scared about the imminent LP
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49 167 (median VRS 8, IQR 6-10), with 60% indicating a VRS ≥8 in relation to how scared they felt
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51 168 (Figure 2A & 2B). 40% of patients described severe pain during the LP (VRS ≥8) with a
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53 169 median pain score of 7 (VRS, IQR 5-8) (Figure 2A & 2C). Additionally, the majority of
54
55 170 patients felt they received insufficient pain relief (85%). Levels of anxiety about future LP's

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3 171 were high (median VRS 7, IQR 4-10), with 47% being extremely anxious (VRS \geq 8) (Figure
4 172 2A & 2D). There was no relationship found between the pre-procedure anxiety levels and the
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6 173 subsequent recalled pain score of the LP.
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9 174 **Setting of LP and pre-procedural information**

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11 175 LPs were predominantly performed in the emergency setting (72%), as opposed to as an
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13 176 elective planned procedure on day-case unit. Importantly the LPs performed in the
14
15 177 emergency setting were associated with significantly greater pain scores compared to
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17 178 elective procedures (VRS median 7, IQR 5-7 vs 6, IQR 4-8 respectively, $p=0.012$).
18

19 179 Only 37% of patients felt well informed about LP pre-procedure (VRS \geq 8); 27% felt poorly
20
21 180 informed (VRS 0-3), and 7% did not feel they were informed at all (VRS 0). Higher LP pain
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23 181 scores (VRS) were significantly associated with patients being poorly informed (Spearman
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25 182 correlation, $r=-0.32$, $p<0.001$) (Figure 3A). Patients felt better informed if they had an elective
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27 183 planned LP compared to a procedure in the emergency setting (median 7, IQR 5-10 versus
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29 184 median 6, IQR 5-10, $p=0.011$).
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31 185 **Difficulty of LP and need for X-ray guided procedure**

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33 186 47% of patients had 2 or more doctors attempt their LP (median 1, IQR 1-2) while 45%
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35 187 had greater than 3 attempts (number of times needle inserted) before success. 10.7% went
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37 188 on to have an X-Ray guided procedure due to failure of the initial LP, and the BMI was
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39 189 significantly higher in this group (mean kg/m^2 40.3 vs. 35.5, $p=0.001$) (Figure 3B). There was
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41 190 only a weak correlation between BMI and how scared a patient was beforehand, how much
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43 191 pain they felt, and how anxious they felt about future LPs (Spearman $r = 0.17$, 0.17 , 0.17
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45 192 respectively, $p<0.001$ for all). Compared to those that had normal LPs, the patients having
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47 193 X-Ray guided procedures felt less informed (VRS median 3 vs 6, $p=0.002$), suffered more
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49 194 pain (VRS median 8 vs 7, $p=0.004$), and were more anxious about future LPs (VRS median
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51 195 9 vs 7, $p=0.003$).
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196 **Grade of Doctor performing LP**

197 Table 2 shows the number of LP attempts by grade of doctor performing the LP. Patients
198 felt more informed when the LP was performed by a Specialist Registrar (SpR) compared to
199 a Junior doctor (median VRS 7 vs 5, $p=0.001$) or Consultant compared to a Junior doctor
200 (median VRS 8 vs 5, $p<0.001$), though there was no significant difference in the pain scores
201 reported. They also suffered from less severe post-LP headaches (SpR vs Junior median
202 VRS 7 vs 8, $p<0.001$, Consultant vs Junior median VRS 6.5 vs 8, $p=0.003$) (Figure 3C), and
203 length of post-LP headache (SpR vs Junior median days 3 vs 6, $p=0.02$, Consultant vs
204 Junior median days 4 vs 6, $p=0.9$) (Figure 3D).

205 **Discussion**

206 This is the first study, to the best of our knowledge, to document the patient experience
207 of diagnostic lumbar punctures in IIH. It has shown that a number of patients are recalling
208 significant pain and anxiety. This morbidity is associated with inadequate pre-procedural
209 information, the environment the LP is performed in (emergency setting being associated
210 with increased pain), and the seniority of the doctor performing the LP.

211 Anaesthetists have long recognised the importance of the patient experience of spinal
212 anaesthesia as an outcome measure and an indicator of quality of care (5) (6) (7). This is
213 reflected in the high satisfaction levels patients report with the procedure (96-97%), which is
214 in stark contrast to the feedback here. The differences between the anaesthetic population
215 and the IIH patient group may be related to the procedure being technically more challenging
216 due to the patient's high BMI, the procedure happening as an emergency and some having
217 multiple LPs during the course of their IIH. It may also be due to anaesthetists having better
218 technical skills due to performing the procedure more often than the doctors (often non-
219 neurologists) performing the LPs in the emergency setting, in addition to more closely
220 supervised and rigorous training .

221 This was a large sample size study (463 responders) where patients could respond
222 anonymously, thus increasing the likelihood of honest reporting of their subjective

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3 223 experiences of the procedure. This cohort reports the LP experience as negative with 40% of
4 224 patients experiencing severe pain (VRS ≥ 8) during the procedure, 85% saying they did not
5 225 receive adequate analgesia and 47% stating they were extremely anxious (VRS ≥ 8) about
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7 226 future LPs.

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10 227 The majority of the group did not feel they received adequate pre-procedural information,
11 228 with 63% not feeling well informed (VRS < 8), and 7% saying that they were not informed at
12 229 all (VRS =0). Patients who were less informed experienced more pain during the procedure.
13
14 230 Although all patients will have undergone a consent process in the UK, this data highlights
15 231 the variable quality of the information disseminated by the physician to the patient. Current
16 232 practices for informing patients about LP are likely to be highly variable across the UK. This
17 233 study highlights a key area where simple changes in clinical practice to ensure all patients
18 234 are provided with detailed pre-procedure information (Box 2) could facilitate improved patient
19 235 care.

20 236 Environment also had a bearing on the patient experience with 72% of LPs being
21 237 performed in the emergency setting; this was associated with the patient feeling less
22 238 informed, and reporting significantly higher pain scores, compared to an elective procedure
23 239 on a day-case unit. The high portion of the respondents who had an LP performed as part of
24 240 an emergency admission in this study likely reflects the UK health care services and clinical
25 241 practice where patients with a flare up in IHH symptoms are typically initially seen in the
26 242 accident and emergency department for initial evaluation and often have a LP as part of their
27 243 evaluation here, or on the acute medical unit. As the study was not designed to determine
28 244 the clinical indications for the LP in each case no further inference can be made here.
29 245 Typically, LP's performed in the emergency setting may be conducted by junior physicians,
30 246 with less experience in conducting LP's than a speciality trained neurologist or anaesthetist.
31 247 This may be a factor contributing to the poorer outcomes from LPs performed in the
32 248 emergency setting.

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35 249 Optimisation of the environment for the patient undergoing LP could therefore positively
36 250 affect their outcome (see Box 1). The day case environment may provide access to doctors

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3 251 adequately trained in performing LPs as well as a less time-pressurised environment. Time
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5 252 to reflect on the procedure and read pre-procedural information, may help improve the
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7 253 overall experience. Although diverting IIH patients away from the emergency setting would
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9 254 likely benefit the majority, it may not be practical for a minority of papilloedema cases where
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11 255 there is progressive or rapid loss of visual function, and the need for acute diagnosis.

12
13 256 The study also suggests that there is also scope for improving our technical skills in LP,
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15 257 as 85% of our cohort stated that they did not receive adequate analgesia, with 45%
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17 258 undergoing greater than 3 attempts (defined as the needle being fully withdrawn between
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19 259 attempts), and 47% having 2 or more doctors attempt the LP. When the LP was performed
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21 260 by a doctor more junior than registrar (30% of the time), the patients felt less informed, and
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23 261 reported more severe and longer lasting post-LP headaches. We acknowledge that the grade
24
25 262 of doctor performing the LP may not be accurately recalled by the patient and maybe more
26
27 263 of a reflection of the patient's confidence in the doctor. However, diverting LPs into the day-
28
29 264 case setting would provide an opportunity where the junior doctors could be appropriately
30
31 265 supervised and trained, which has been shown to increase their ability to perform the
32
33 266 procedure (8).

34
35 267 In this cohort, 10.7% of patients reported having an x-ray guided procedure due to failure
36
37 268 of the initial LP, with the BMI being significantly higher in this group (mean 40.3kg/m² vs.
38
39 269 35.5kg/m², p=0.001). This finding is in keeping with a recent study which showed a strong
40
41 270 correlation between BMI and procedure failure, with half of the failed LPs occurring in
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43 271 patients with a BMI greater than 35kg/m² (9). The inability to palpate landmarks in obese
44
45 272 patients is likely to be a significant driver of this correlation (10). The x-ray guided LP group
46
47 273 felt less informed, reported more pain, and were more likely to feel anxious about future LPs;
48
49 274 findings most likely due to the number of failed attempts before the x-ray guided procedure.
50
51 275 The growing evidence base for use of ultrasound guidance, particularly in patients with a
52
53 276 higher BMI and absence of landmarks (11), suggests that its use in the IIH patient cohort
54
55 277 may increase the success rate of the initial LP and decrease the number that require x-ray
56
57 278 guided procedures (see Box 1).

279 For clinical care a positive experience of a diagnostic LP will positively impact on the
280 patient's future engagement with healthcare services, whilst in IIH research LP experience
281 affects recruitment to clinical trials (12); it is therefore critical that clinicians optimise patient
282 care.

283 **Limitations**

284 The main limitation of the study is its retrospective nature and as such the results are
285 likely susceptible to recall bias. Interpretation of some of the study questions is problematic:
286 for example, for questions such as the number of attempts for a lumbar puncture and the
287 seniority of the doctor performing the procedure, the respondents may not accurately know
288 the answer.

289 **Conclusion**

290 There has been a growing consensus in recent years that if healthcare services are to
291 better deliver patient-centred care then research needs to be more reflective of patients'
292 needs and concerns (13)(14). This study was commissioned by the IIH patient group and is
293 the first to document the patient experience of diagnostic lumbar punctures in IIH. It
294 documents experiences of significant pain and anxiety associated with both inadequate pre-
295 procedural information and the setting the LP is performed in. The study suggests a number
296 of practical steps that may improve the patient experience of LPs.

Box 2: Recommendations for improving patient experience of diagnostic LP in IIH

- Providing enhanced pre-procedural information.
- Where possible, diverting emergency department LPs to elective procedures on dedicated day case units.
- Simulation training for doctors and specialist nurses to develop appropriate technical (including ultrasound guidance) and human factor skills (such as

communication, empathy and leadership) for performing LPs in a technically difficult patient cohort.

- Implementing widespread patient reported outcome measures for LPs to guide the need for service improvements and training needs.

297

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333 **Competing interests statement**

334 None Declared.
335

336 **Author's contribution to the research**

337 **William J. Scotton** Compilation of the survey results; statistical analysis; interpretation of
338 the results and drafting the manuscript

339 **Susan P. Mollan** Conception and design of the survey; critical review of the manuscript

340 **Thomas Walters** Compilation of the survey results and statistical analysis

341 **Sandra Doughty** Conception and design of the survey

342 **Peter Nightingale** Statistical analysis

343 **Hannah Botfield** Statistical analysis and interpretation of the results

344 **Keira Markey:** Interpretation off the results and drafting of the manuscript

345 **Andreas Yiangou:** Interpretation off the results and drafting of the manuscript

346 **Shelly Williamson** Conception and design of the survey

347 **Alexandra J. Sinclair** Conception and design of the survey; interpretation of the results and
 348 critical review of the manuscript

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350 **All authors have read and approved the final manuscript.**

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353

354 **Figure 1:** Baseline characteristics of eligible responders

355

356 **Table 1:** Baseline characteristics of eligible responders

Variable	No. (%)
	n=463
Age, mean, years (SD)	32.9 (8.9)
Female sex	456 (98.5%)
Weight, mean, kg (SD)	97.2 (22.5)
BMI, mean (SD)	36.0 (8.3)
LPs since diagnosis, median (IQR)	4 (1-11)
LPs per year since diagnosis, median (IQR)	1 (1-4)

357

358 **Figure 2:** Patients' expectations and experience of LP. (A) Median VRS (0-10, IQR) for how
 359 scared patient was before LP, how painful the LP was and how anxious they were about
 360 future LPs. (B) Number of patients that were mildly (0-3), moderately (4-7), or very scared
 361 (8-10) before having an LP. (C) Number of patients that experienced mild (VRS 0-3),
 362 moderate (VRS 4-7) or severe (VRS 8-10) pain during the LP. (D) Number of patients that
 363 were mildly (VRS 0-3), moderately (VRS 4-7) or very anxious (VRS 8-10) about future LPs.
 364 [VRS 0=minimum and 10 maximal score]

365

366 **Figure 3:** X-Ray guided LPs, and relationship of pre-procedural information and grade of
 367 doctor performing LP to patient experience. (A) For all patients surveyed, association
 368 between how well-informed patient was before LP, and how painful LP was (median VRS,
 369 IQR, min-max). (B) BMI (median, IQR) and association with whether patient had X-Ray
 370 guided LP. (C) Grade of doctor performing LP and duration of post-LP headache (days,
 371 median, IQR). (D) Grade of doctor performing LP and severity of post-LP headache. ns
 372 $p>0.05$, * $p\leq 0.05$, ** $p\leq 0.01$, *** $p\leq 0.001$, [VRS 0=minimum and 10=maximal score].

373 **Table 2:** Number of LP attempts by grade of doctor

Number of LP attempts	Grade of Doctor (% of total patients [n=463])				
	Unknown	Junior	Registrar	Consultant	Total
1-3	13.0%	9.1%	15.1%	11.0%	48.2%
4-6	4.8%	5.2%	6.3%	3.9%	20.1%
7-9	2.6%	1.9%	3.0%	1.7%	9.3%
10-14	0.6%	1.7%	1.3%	0.4%	4.1%
15-19	0.4%	1.1%	0.4%	0.0%	1.9%
20+	0.6%	1.1%	0.4%	0.2%	2.4%
Unknown	4.5%	1.1%	3.2%	5.2%	14.0%
Total	26.6%	21.2%	29.8%	22.5%	100%

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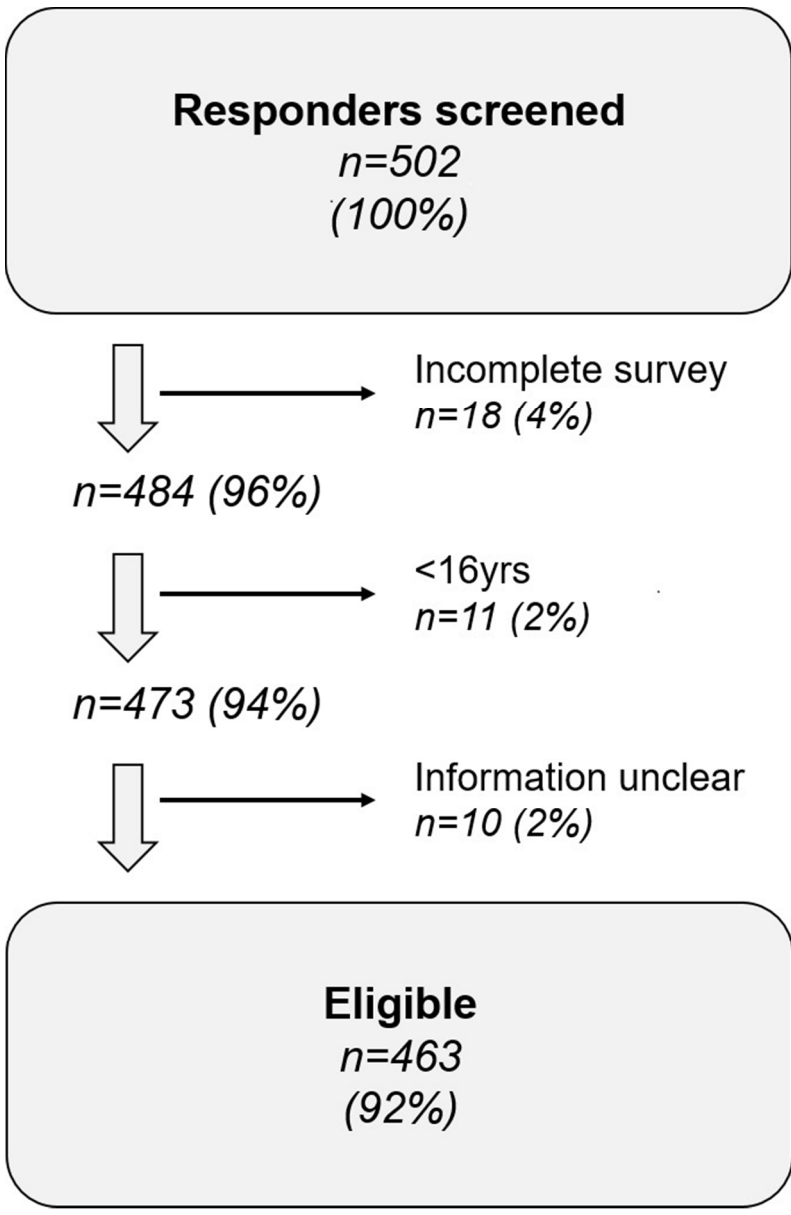


Figure 1: Baseline characteristics of eligible responders.

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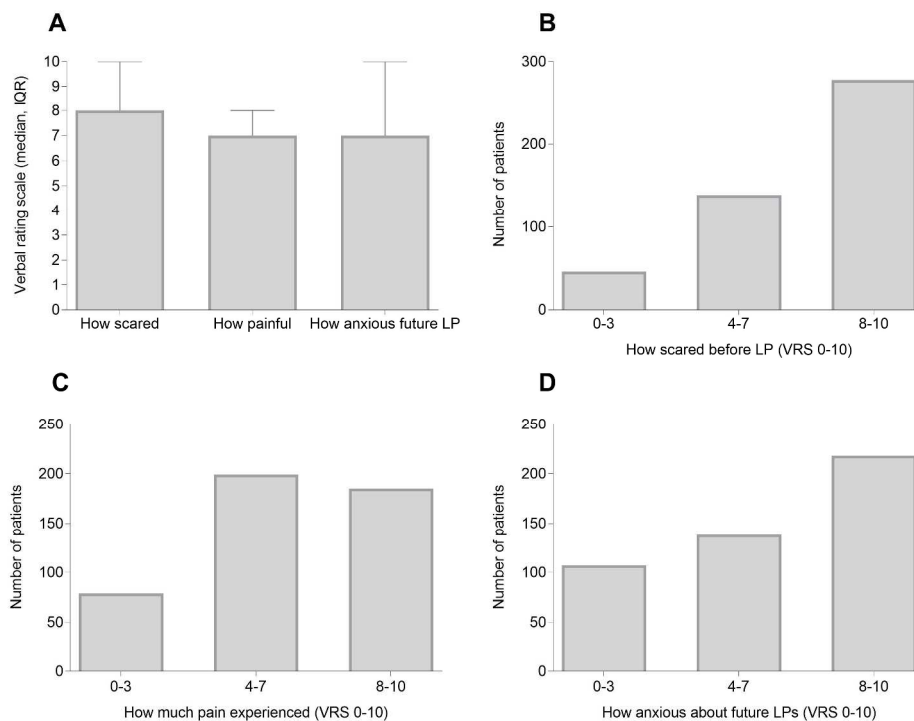


Figure 2: Patients' expectations and experience of LP. (A) Median VRS (0-10, IQR) for how scared patient was before LP, how painful the LP was and how anxious they were about future LPs. (B) Number of patients that were mildly (0-3), moderately (4-7), or very scared (8-10) before having an LP. (C) Number of patients that experienced mild (VRS 0-3), moderate (VRS 4-7) or severe (VRS 8-10) pain during the LP. (D) Number of patients that were mildly (VRS 0-3), moderately (VRS 4-7) or very anxious (VRS 8-10) about future LPs. [VRS 0=minimum and 10 maximal score].

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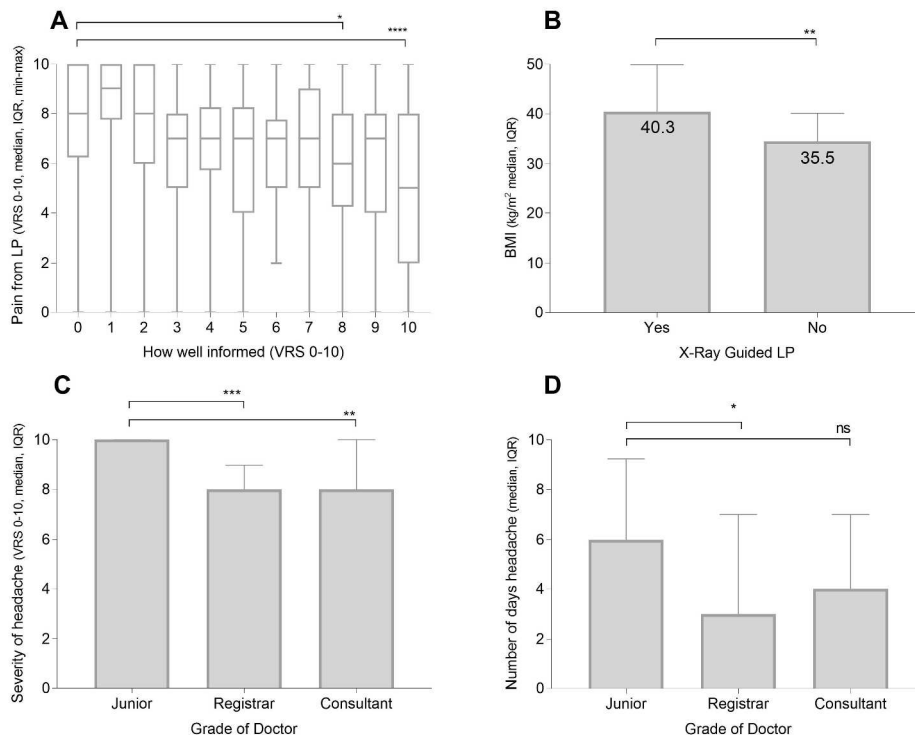


Figure 3: X-Ray guided LPs, and relationship of pre-procedural information and grade of doctor performing LP to patient experience. (A) For all patients surveyed, association between how well-informed patient was before LP, and how painful LP was (median VRS, IQR, min-max). (B) BMI (median, IQR) and association with whether patient had X-Ray guided LP. (C) Grade of doctor performing LP and duration of post-LP headache (days, median, IQR). (D) Grade of doctor performing LP and severity of post-LP headache. ns $p > 0.05$, * $p \leq 0.05$, ** $p \leq 0.01$, *** $p \leq 0.001$, [VRS 0=minimum and 10=maximal score].

280x217mm (300 x 300 DPI)

IIHUK Online Questionnaire

Demographics

1. How old were you at time of diagnostic LP?
2. What was date of your first lumbar puncture? (Do not worry if you cannot remember the exact day, but please specify month and year)
3. Since your first diagnostic LP, how many LPs have you had? (Please approximate if not sure of the exact number)
4. What is your height (metres)?
5. What is your weight (kg)?

Details of lumbar puncture

1. Was your first admission regarding your LP planned (you were sent an appointment by your doctor) or as an emergency?
2. Where in the hospital did the first LP take place? (Emergency department, Ward or In Theatre)
3. How many different doctors attempted your diagnosing LP? (i.e how many different doctors tried inserting a needle)
4. How many attempts were made to get a diagnostic LP? (An attempt being defined as a needle being inserted)
5. If the initial LP failed to get a reading did you go on to have it done in theatre under X-ray guidance?

Patient experience of lumbar puncture

1. How frightened were you about the thought of the LP before the procedure on a scale 0-10? (0 being not frightened at all, 10 being the most scared you've ever felt)
2. How well do you feel you were informed about the procedure prior to the LP on a scale 0-10? (0 being not informed, 10 being fully informed)
3. Was adequate analgesia (i.e. local anaesthetic) used in your diagnosing LP?

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4. How much pain did you experience during the LP on a scale of 0-10? (0 being pain free, 10 being worst pain ever experienced)
5. On a scale of 0-10, how anxious do you feel about having LPs in the future? (0 being not anxious, 10 being the most anxious you've ever felt)

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (Pg1) (b) Provide in the abstract an informative and balanced summary of what was done and what was found (Pg 3-4)
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported (Pg5)
Objectives	3	State specific objectives, including any prespecified hypotheses (Pg5)
Methods		
Study design	4	Present key elements of study design early in the paper (Pg5-6)
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection (Pg6)
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants (Pg6 & Figure 1) (b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable (Pg5-6)
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group (Pg5-6)
Bias	9	Describe any efforts to address potential sources of bias (Pg11)
Study size	10	Explain how the study size was arrived at (Pg6)
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why (Pg 6)
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (Pg6) (b) Describe any methods used to examine subgroups and interactions (Pg6) (c) Explain how missing data were addressed (Pg6 – responders with missing data excluded from study) (d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy (n/a) (e) Describe any sensitivity analyses (n/a)

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Results

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (Pg 7 & Figure 1) (b) Give reasons for non-participation at each stage (see above) (c) Consider use of a flow diagram (Figure 1)
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (Pg 7 & Table 1) (b) Indicate number of participants with missing data for each variable of interest (Pg 7) (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures (Pg7-8)
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (Pg7-8) (b) Report category boundaries when continuous variables were categorized (Pg7-8) (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period (n/a)
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses (n/a)

Discussion

Key results	18	Summarise key results with reference to study objectives (Pg 8-10)
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias (Pg11)
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence (Pg11)
Generalisability	21	Discuss the generalisability (external validity) of the study results (Pg9)

Other information

Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based (Pg2)
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*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Characterising the patient experience of diagnostic lumbar puncture in Idiopathic Intracranial Hypertension: a cross-sectional online survey.

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Date Submitted by the Author:	11-Apr-2018
Complete List of Authors:	<p>Scotton, William; University of Birmingham, Metabolic Neurology, Institute of Metabolism and Systems Research; University Hospitals Birmingham NHS Foundation Trust, Department of Neurology</p> <p>Mollan, Susan; University of Birmingham, Metabolic Neurology, Institute of Metabolism and Systems Research; Birmingham Neuro-Ophthalmology Unit, Ophthalmology Department, University Hospitals Birmingham NHS Trust, Queen Elizabeth Hospital Birmingham</p> <p>Walters, Thomas; University of Birmingham, Metabolic Neurology, Institute of Metabolism and Systems Research</p> <p>Doughty, Sandra; Idiopathic Intracranial Hypertension UK</p> <p>Botfield, Hannah; University of Birmingham, Metabolic Neurology, Institute of Metabolism and Systems Research; Centre for Endocrinology, Diabetes and Metabolism, Birmingham Health Partners</p> <p>Markey, Keira; University of Birmingham, Metabolic Neurology, Institute of Metabolism and Systems Research; University Hospitals Birmingham NHS Foundation Trust, Department of Neurology</p> <p>Yiangou, Andreas; University of Birmingham, Metabolic Neurology, Institute of Metabolism and Systems Research; University Hospitals Birmingham NHS Foundation Trust, Department of Neurology</p> <p>Williamson, Shelley; Idiopathic Intracranial Hypertension UK</p> <p>Sinclair, AJ; University of Birmingham, Metabolic Neurology, Institute of Metabolism and Systems Research; Centre for Endocrinology, Diabetes and Metabolism, Birmingham Health Partners</p>
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Keywords:	Adult neurology < NEUROLOGY, Neuro-ophthalmology < NEUROLOGY, NEUROPATHOLOGY, Neuro-ophthalmology < OPHTHALMOLOGY

SCHOLARONE™
Manuscripts

Title: Characterising the patient experience of diagnostic lumbar puncture in Idiopathic Intracranial Hypertension: a cross-sectional online survey.

Authors: William J. Scotton^{1,2}, Susan P. Mollan^{1,3}, Thomas Walters¹, Sandra Doughty⁴, Hannah Botfield^{1,5}, Keira Markey^{1,2}, Andreas Yiangou^{1,2}, *Shelly Williamson⁴, *Alexandra J. Sinclair^{1,5}.

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1
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17
18 36 without which this study would not have been possible
19
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21 37

22 38 **Competing interests statement**

23
24 39 None Declared.
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28 41 **Author's contribution to the research**

29
30 42 **William J. Scotton:** Compilation of the survey results; statistical analysis; interpretation of the results and drafting the
31
32 43 manuscript

33 44 **Susan P. Mollan:** Conception and design of the survey; critical review of the manuscript

34 45 **Thomas Walters:** Compilation of the survey results and statistical analysis

35 46 **Sandra Doughty:** Conception and design of the survey

36 47 **Hannah Botfield** Statistical analysis and interpretation of the results

37 48 **Keira Markey:** Interpretation off the results and drafting of the manuscript

38 49 **Andreas Yiangou:** Interpretation off the results and drafting of the manuscript

39 50 **Shelly Williamson:** Conception and design of the survey

40 51 **Alexandra J. Sinclair:** Conception and design of the survey; interpretation of the results and critical review of the manuscript
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46 53 **All authors have read and approved the final manuscript.**

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48 54 **Data sharing statement:** We are happy to share all data, including raw data if requested.
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2
3 56 **Abstract**

4
5 57 **Objectives**

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8 58 Patients with idiopathic intracranial hypertension (IIH) usually require multiple lumbar
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10 59 punctures during the course of their disease, and often report significant morbidity
11
12 60 associated with the procedure. The aim of this study was to assess the patient's experience
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14 61 of diagnostic lumbar puncture (LP) in IIH.

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16 62 **Design, methods and participants**

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18 63 A cross-sectional study of IIH patients was conducted using an anonymous online survey,
19
20 64 with the questions designed in collaboration with IIH UK (the UK IIH charity). Responses
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22 65 were collated over a two-month period from April to May 2015. Patients were asked to
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24 66 quantify responses using a verbal rating score (VRS) 0-10 with 0 being the minimum and 10
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26 67 the maximum score.

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29 68 **Results**

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31 69 502 patients responded to the survey, of which 463 were analysed for this study. 40% of
32
33 70 patients described severe pain during the LP (VRS ≥ 8), and the median pain score during
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35 71 the LP was 7 (VRS, IQR 5-7). The majority of patients felt they received insufficient pain
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37 72 relief (85%). Levels of anxiety about future LPs were high (median VRS 7, IQR 4-10), with
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39 73 47% being extremely anxious (VRS ≥ 8). LPs performed as an emergency were associated
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41 74 with significantly greater pain scores compared to elective procedures (median 7, IQR 5-7
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43 75 vs. 6, IQR 4-8, $p=0.012$). 10.7% went on to have an X-Ray guided procedure due to failure
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45 76 of the initial LP, and the BMI was significantly higher in this group (mean kg/m^2 40.3 vs. 35.5,
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47 77 $p=0.001$). Higher LP pain scores (VRS) were significantly associated with poorly informed
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49 78 patients (Spearman correlation, $r=-0.32$, $p<0.001$). Patients felt more informed when the LP
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51 79 was performed by a Specialist Registrar compared to a Junior Doctor (median 7 vs. 5,
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53 80 $p=0.001$) or a Consultant compared to a Junior Doctor (median 8 vs. 5, $p<0.001$).

81 Conclusions

82 This study was commissioned by the IIH patient group and is the first to document the
83 patient experience of diagnostic lumbar punctures in IIH. It shows that the majority of these
84 patients are experiencing significant morbidity from pain and anxiety. Patient experience of
85 LP may be improved through changing clinical practice to include universal detailed pre-
86 procedural information, and where possible, avoiding emergency LPs in favour of LPs
87 booked on an elective day case unit.

88

Strengths and limitations of this study

- This large sample size UK survey is the first known to directly and specifically document the patient experience of diagnostic lumbar punctures in IIH, and it confirms that a significant number of these patients are experiencing morbidity from pain and anxiety related to the procedure.
- The use of an online questionnaire ensured anonymity, thus increasing the likelihood of honest reporting by patients of their subjective experiences of the procedure.
- Given the self-report nature of this study, the results may be susceptible to recall bias, thus limiting the generalisability of our findings.

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93 Introduction

94 Idiopathic intracranial hypertension (IIH) is characterised by raised intracranial pressure
95 (ICP) which can cause papilloedema with significant visual loss in some, as well as severe
96 disabling headaches which significantly impact on quality of life in the majority (1)(2). The
97 diagnostic criteria for IIH is based on an elevated lumbar puncture (LP) opening pressure
98 (≥ 250 mm CSF in adults) in a properly performed lumbar puncture (3).

99 Many patients have multiple LPs during the disease course typically to assess disease
100 severity, and in some cases as a therapeutic strategy. Established complications of LPs
101 include local discomfort, low pressure headaches and more rarely infection or local
102 haemorrhage (4). We have been made aware of an additional significant complication of LPs
103 voiced by the patients themselves. The patients describe a very negative experience of LPs
104 associated with anxiety, fear and pain during and after the procedure. The National charity
105 IIH UK (Registered Charity in England and Wales no 1143522 & Scotland SCO43294)
106 approached us with concerns about the IIH patient experience of LPs. Patient experience of
107 spinal anaesthesia and LP has previously been studied (5)(6). However, the experience of
108 IIH patients undergoing LP has not been evaluated. LPs are typically more technically
109 challenging in the IIH population as over 90% of these patients are obese (3).

110 The aim of this study was to assess the patient experience of diagnostic LPs in IIH. We
111 aimed to disseminate this evidence to medical professionals to increase awareness of this
112 potential morbidity of LP in IIH patients. Furthermore, we aimed to use evidence from this
113 study as a catalyst to drive improvements in patient care.

114 Material and Methods

115 Public and Patient Involvement

116 This research was initiated, designed and conducted by IIH UK, a charity that supports
117 IIH patients and carers. The charity agreed at a Trustee meeting to design a survey to
118 investigate the magnitude of lumbar puncture related anxiety in response to their
119 overwhelming messages from patients. When the first survey was performed the Trustees

120 recognised that they would need help both in analysis of the data as well as asking
121 additional questions. A further survey was therefore conducted. The clinical researchers at
122 the University Hospitals Birmingham provided support with statistical analysis and critical
123 review of the data.

124 Dissemination of the results was planned via physician and patient meetings, through
125 medical and patient lead social media, and on the IIH UK patients' charity website.

126 **Study Design**

127 The cross-sectional study was conducted using an online survey. IIH UK sent a survey
128 monkey questionnaire through social media outlets (Facebook, Twitter (@IIHUK) and IIH UK
129 charity website (www.iih.org.uk) and allowed a two-month period from 1st April to 31st May
130 2015 for responses. Questionnaires were excluded if the respondents were under the age of
131 16 years or the survey was incomplete (missing key data fields) or uninterpretable.
132 Anonymised data was analysed by the clinical team with input from the clinical research
133 facility statistician (PN). As the charity board had already agreed with their members
134 beforehand, and both surveys instructed the respondents that the information would be used
135 to be published within the medical literature, no further ethical approval was required.

136 The questionnaire (see supplementary document) detailed baseline demographic details
137 (age, weight and height), and details of the LP (emergency versus planned procedure,
138 hospital setting, number of attempts, whether went on to have an X-Ray guided procedure
139 and seniority of doctor performing). Data on anxiety (for the LP and future LPs), pain
140 experienced and extent of understanding of the procedure was also collected. Patients were
141 asked to quantify responses using a verbal rating score (VRS) 0-10 with 0 being the
142 minimum and 10 the maximum score.

143 **Statistical analysis**

144 Statistical analysis was performed using SPSS versions 24 (SPSS Inc., Chicago, IL,
145 USA) and GraphPad Prism 7 for Windows (GraphPad Software Inc., La Jolla, CA, USA).
146 Assessment of data for normality was performed for each analysis. Normally distributed data

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3 147 was reported using mean and standard deviation (SD), and non-normally distributed data
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5 148 was reported using median and interquartile range (IQR). For all comparisons of continuous
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7 149 variables, a non-parametric test was used due to non-normality of data distribution. For
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9 150 comparison of two medians Mann-Whitney U tests were used, whilst for comparison of
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11 151 multiple medians Kruskal-Wallis H tests were used. Spearman's rank-order correlation was
12
13 152 used to analyse the correlation between how informed the patients were and how much pain
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15 153 they felt, as well as between BMI and how scared a patient was beforehand, how much pain
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17 154 they felt, and how anxious they felt about future LPs. For comparison of categorical variables
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19 155 Chi square tests were used. Values were considered statistically significant when P values
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21 156 were less than 0.05.

22 23 157 **Results**

24 25 158 **Demographics**

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28 159 There were 502 responders to the study, of which 463 were eligible for analysis. 18
29
30 160 responders did not complete the survey, 11 were under the age of 16 years, and 10 gave
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32 161 incomplete answers or ambiguous information that could not be objectively interpreted
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34 162 (Figure 1). The mean age was 33 years (SD 8.9), 98.5% were female (n=456), with a mean
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36 163 weight of 97.4kg (SD 22.3), and a mean Body Mass Index (BMI) of 36 kg/m² (SD 8.3). The
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38 164 median number of LPs undergone since diagnosis was 4 (inter-quartile range [IQR] 1-11),
39
40 165 though 3.1% of patients (n=15) reported more than 50 LPs. When number of LPs was
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42 166 adjusted to reflect length of disease, the median number of LPs per year since diagnosis
43
44 167 was 1.3 (IQR 0.3-3.6) (Table 1).

45 46 168 **Pain, Anxiety & Analgesia**

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48
49 169 The majority of patients indicated they were extremely scared about the imminent LP
50
51 170 (median VRS 8, IQR 6-10), with 60% indicating a VRS ≥8 in relation to how scared they felt
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53 171 (Figure 2A & 2B). 40% of patients described severe pain during the LP (VRS ≥8) with a
54
55 172 median pain score of 7 (VRS, IQR 5-8) (Figure 2A & 2C). Additionally, the majority of

173 patients felt they received insufficient pain relief (85%). Levels of anxiety about future LPs
174 were high (median VRS 7, IQR 4-10), with 47% being extremely anxious (VRS ≥ 8) (Figure
175 2A & 2D). There was no relationship found between the pre-procedure anxiety levels and the
176 subsequent recalled pain score of the LP.

177 **Setting of LP and pre-procedural information**

178 LPs were predominantly performed in the emergency setting (72%), as opposed to as an
179 elective planned procedure on day-case unit. Importantly the LPs performed in the
180 emergency setting were associated with significantly greater pain scores compared to
181 elective procedures (VRS median 7, IQR 5-7 vs 6, IQR 4-8 respectively, $p=0.012$).

182 Only 37% of patients felt well informed about LP pre-procedure (VRS ≥ 8); 27% felt poorly
183 informed (VRS 0-3), and 7% did not feel they were informed at all (VRS 0). Higher LP pain
184 scores (VRS) were significantly associated with patients being poorly informed (Spearman
185 correlation, $r=-0.32$, $p<0.001$) (Figure 3A). Patients felt better informed if they had an elective
186 planned LP compared to a procedure in the emergency setting (median 7, IQR 5-10 versus
187 median 6, IQR 5-10, $p=0.011$).

188 **Difficulty of LP and need for X-ray guided procedure**

189 47% of patients had 2 or more doctors attempt their LP (median 1, IQR 1-2) while 45%
190 had greater than 3 attempts (number of times needle inserted) before success. 10.7% went
191 on to have an X-Ray guided procedure due to failure of the initial LP, and the BMI was
192 significantly higher in this group (mean kg/m^2 40.3 vs. 35.5, $p=0.001$) (Figure 3B). There was
193 only a weak correlation between BMI and how scared a patient was beforehand, how much
194 pain they felt, and how anxious they felt about future LPs (Spearman $r = 0.17$, 0.17 , 0.17
195 respectively, $p<0.001$ for all). Compared to those that had normal LPs, the patients having
196 X-Ray guided procedures felt less informed (VRS median 3 vs 6, $p=0.002$), suffered more
197 pain (VRS median 8 vs 7, $p=0.004$), and were more anxious about future LPs (VRS median
198 9 vs 7, $p=0.003$).

199 **Grade of Doctor performing LP**

200 Table 2 shows the number of LP attempts by grade of doctor performing the LP. Patients
201 felt more informed when the LP was performed by a Specialist Registrar (SpR) compared to
202 a Junior doctor (median VRS 7 vs 5, $p=0.001$) or a Consultant compared to a Junior doctor
203 (median VRS 8 vs 5, $p<0.001$), though there was no significant difference in the pain scores
204 reported. They also suffered from less severe post-LP headaches (SpR vs Junior median
205 VRS 7 vs 8, $p<0.001$, Consultant vs Junior median VRS 6.5 vs 8, $p=0.003$) (Figure 3C), and
206 length of post-LP headache (SpR vs Junior median days 3 vs 6, $p=0.02$, Consultant vs
207 Junior median days 4 vs 6, $p=0.9$) (Figure 3D).

208 **Discussion**

209 This is the first study, to the best of our knowledge, to document the patient experience
210 of diagnostic lumbar punctures in IIH. It has shown that a number of patients are recalling
211 significant pain and anxiety. This morbidity is associated with inadequate pre-procedural
212 information, the environment the LP is performed in (emergency setting being associated
213 with increased pain), and the seniority of the doctor performing the LP.

214 Anaesthetists have long recognised the importance of the patient experience of spinal
215 anaesthesia as an outcome measure and an indicator of quality of care (5)(6)(7). This is
216 reflected in the high satisfaction levels patients report with the procedure (96-97%), which is
217 in stark contrast to the feedback here. The differences between the anaesthetic population
218 and the IIH patient group may be related to the procedure being technically more challenging
219 due to the patient's high BMI, the procedure happening as an emergency and some having
220 multiple LPs during the course of their IIH. It may also be due to anaesthetists having better
221 technical skills due to performing the procedure more often than the doctors (often non-
222 neurologists) performing the LPs in the emergency setting, in addition to more closely
223 supervised and rigorous training.

224 This was a large sample size study (463 responders) where patients could respond
225 anonymously, thus increasing the likelihood of honest reporting of their subjective

226 experiences of the procedure. This cohort reports the LP experience as negative with 40% of
227 patients experiencing severe pain (VRS ≥ 8) during the procedure, 85% saying they did not
228 receive adequate analgesia and 47% stating they were extremely anxious (VRS ≥ 8) about
229 future LPs.

230 The majority of the group did not feel they received adequate pre-procedural information,
231 with 63% not feeling well informed (VRS < 8), and 7% saying that they were not informed at
232 all (VRS =0). Patients who were less informed experienced more pain during the procedure.
233 Although all patients will have undergone a consent process in the UK, this data highlights
234 the variable quality of the information disseminated by the physician to the patient. Current
235 practices for informing patients about LP are likely to be highly variable across the UK. This
236 study highlights a key area where simple changes in clinical practice to ensure all patients
237 are provided with detailed pre-procedure information could facilitate improved patient care.

238 Environment also had a bearing on the patient experience with 72% of LPs being
239 performed in the emergency setting; this was associated with the patient feeling less
240 informed, and reporting significantly higher pain scores, compared to an elective procedure
241 on a day-case unit. The high portion of the respondents who had an LP performed as part of
242 an emergency admission in this study likely reflects the UK health care services and clinical
243 practice where patients with a flare up in IHH symptoms are typically initially seen in the
244 accident and emergency department for initial evaluation and often have a LP as part of their
245 evaluation here, or on the acute medical unit. As the study was not designed to determine
246 the clinical indications for the LP in each case no further inference can be made here.
247 Typically LPs performed in the emergency setting may be conducted by junior physicians,
248 with less experience in conducting LPs than a speciality trained neurologist or anaesthetist.
249 This may be a factor contributing to the poorer outcomes from LPs performed in the
250 emergency setting.

251 Optimisation of the environment for the patient undergoing LP could therefore positively
252 affect their outcome. The day case environment may provide access to doctors adequately
253 trained in performing LPs as well as a less time-pressurised environment. Time to reflect on

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3 254 the procedure and read pre-procedural information, may help improve the overall
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5 255 experience. Although diverting IIH patients away from the emergency setting would likely
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7 256 benefit the majority, it may not be practical for a minority of papilloedema cases where there
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9 257 is progressive or rapid loss of visual function, and the need for acute diagnosis.

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11 258 The study also suggests that there is also scope for improving our technical skills in LP,
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13 259 as 85% of our cohort stated that they did not receive adequate analgesia, with 45%
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15 260 undergoing greater than 3 attempts (defined as the needle being fully withdrawn between
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17 261 attempts), and 47% having 2 or more doctors attempt the LP. When the LP was performed
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19 262 by a doctor more junior than registrar (30% of the time), the patients felt less informed, and
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21 263 reported more severe and longer lasting post-LP headaches. We acknowledge that the grade
22
23 264 of doctor performing the LP may not be accurately recalled by the patient and maybe more
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25 265 of a reflection of the patient's confidence in the doctor. However diverting LPs into the day-
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27 266 case setting would provide an opportunity where the junior doctors could be appropriately
28
29 267 supervised and trained, which has been shown to increase their ability to perform the
30
31 268 procedure (8).

32
33 269 In this cohort 10.7% of patients reported having an x-ray guided procedure due to failure
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35 270 of the initial LP, with the BMI being significantly higher in this group (mean 40.3kg/m² vs.
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37 271 35.5kg/m², p=0.001). This finding is in keeping with a recent study which showed a strong
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39 272 correlation between BMI and procedure failure, with half of the failed LPs occurring in
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41 273 patients with a BMI greater than 35kg/m² (9). The inability to palpate landmarks in obese
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43 274 patients is likely to be a significant driver of this correlation (10). The x-ray guided LP group
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45 275 felt less informed, reported more pain, and were more likely to feel anxious about future LPs;
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47 276 findings most likely due to the number of failed attempts before the x-ray guided procedure.
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49 277 The growing evidence base for use of ultrasound guidance, particularly in patients with a
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51 278 higher BMI and absence of landmarks (11), suggests that its use in the IIH patient cohort
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53 279 may increase the success rate of the initial LP and decrease the number that require x-ray
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55 280 guided procedures.

281 For clinical care a positive experience of a diagnostic LP will positively impact on the
282 patient's future engagement with healthcare services, whilst in IIH research LP experience
283 affects recruitment to clinical trials (12); it is therefore critical that clinicians optimise patient
284 care.

285 **Limitations**

286 Given the self-report nature of this study the results are likely susceptible to recall bias.
287 Interpretation of some of the study questions is problematic: for example, for questions such
288 as the number of attempts for a lumbar puncture and the seniority of the doctor performing
289 the procedure, the respondents may not accurately know the answer.

290 **Conclusion**

291 There has been a growing consensus in recent years that if healthcare services are to
292 better deliver patient-centred care then research needs to be more reflective of patients'
293 needs and concerns (13)(14). This study was commissioned by the IIH patient group and is
294 the first to document the patient experience of diagnostic lumbar punctures in IIH. It
295 documents experiences of significant pain and anxiety associated with both inadequate pre-
296 procedural information and the setting the LP is performed in. The study suggests a number
297 of practical steps that may improve the patient experience of LPs.

Recommendations for improving patient experience of diagnostic LP in IIH

- Providing enhanced pre-procedural information.
- Where possible, diverting emergency department LPs to elective procedures on dedicated day case units.
- Simulation training for doctors and specialist nurses to develop appropriate technical (including ultrasound guidance) and human factor skills (such as communication, empathy and leadership) for performing LPs in a technically difficult patient cohort.

- Implementing widespread patient reported outcome measures for LPs to guide the need for service improvements and training needs.

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334 **Competing interests statement**

335 None Declared.
336

337 **Author's contribution to the research**

338 **William J. Scotton** Compilation of the survey results; statistical analysis; interpretation of
339 the results and drafting the manuscript

340 **Susan P. Mollan** Conception and design of the survey; critical review of the manuscript

341 **Thomas Walters** Compilation of the survey results and statistical analysis

342 **Sandra Doughty** Conception and design of the survey

343 **Hannah Botfield** Statistical analysis and interpretation of the results

344 **Keira Markey:** Interpretation off the results and drafting of the manuscript

345 **Andreas Yiangou:** Interpretation off the results and drafting of the manuscript

346 **Shelly Williamson** Conception and design of the survey

347 **Alexandra J. Sinclair** Conception and design of the survey; interpretation of the results and
348 critical review of the manuscript

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350 **All authors have read and approved the final manuscript.**

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354 **Figure 1:** Baseline characteristics of eligible responders

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356 **Table 1:** Baseline characteristics of eligible responders

Variable	No. (%) n=463
Age, mean, years (SD)	32.9 (8.9)
Female sex	456 (98.5%)
Weight, mean, kg (SD)	97.2 (22.5)
BMI, mean (SD)	36.0 (8.3)
LPs since diagnosis, median (IQR)	4 (1-11)
LPs per year since diagnosis, median (IQR)	1 (1-4)

357

358 **Figure 2:** Patients' expectations and experience of LP. (A) Median VRS (0-10, IQR) for how
 359 scared patient was before LP, how painful the LP was and how anxious they were about
 360 future LPs. (B) Number of patients that were mildly (0-3), moderately (4-7), or very scared
 361 (8-10) before having an LP. (C) Number of patients that experienced mild (VRS 0-3),
 362 moderate (VRS 4-7) or severe (VRS 8-10) pain during the LP. (D) Number of patients that
 363 were mildly (VRS 0-3), moderately (VRS 4-7) or very anxious (VRS 8-10) about future LPs.
 364 [VRS 0=minimum and 10 maximal score]

365

366 **Figure 3:** X-Ray guided LPs, and relationship of pre-procedural information and grade of
 367 doctor performing LP to patient experience. (A) For all patients surveyed, association
 368 between how well-informed patient was before LP, and how painful LP was (median VRS,
 369 IQR, min-max). (B) BMI (median, IQR) and association with whether patient had X-Ray

370 guided LP. (C) Grade of doctor performing LP and duration of post-LP headache (days,
 371 median, IQR). (D) Grade of doctor performing LP and severity of post-LP headache. ns
 372 $p > 0.05$, * $p \leq 0.05$, ** $p \leq 0.01$, *** $p \leq 0.001$, [VRS 0=minimum and 10=maximal score].

373 **Table 2:** Number of LP attempts by grade of doctor

Number of LP attempts	Grade of Doctor (% of total patients [n=463])				
	Unknown	Junior	Registrar	Consultant	Total
1-3	13.0%	9.1%	15.1%	11.0%	48.2%
4-6	4.8%	5.2%	6.3%	3.9%	20.1%
7-9	2.6%	1.9%	3.0%	1.7%	9.3%
10-14	0.6%	1.7%	1.3%	0.4%	4.1%
15-19	0.4%	1.1%	0.4%	0.0%	1.9%
20+	0.6%	1.1%	0.4%	0.2%	2.4%
Unknown	4.5%	1.1%	3.2%	5.2%	14.0%
Total	26.6%	21.2%	29.8%	22.5%	100%

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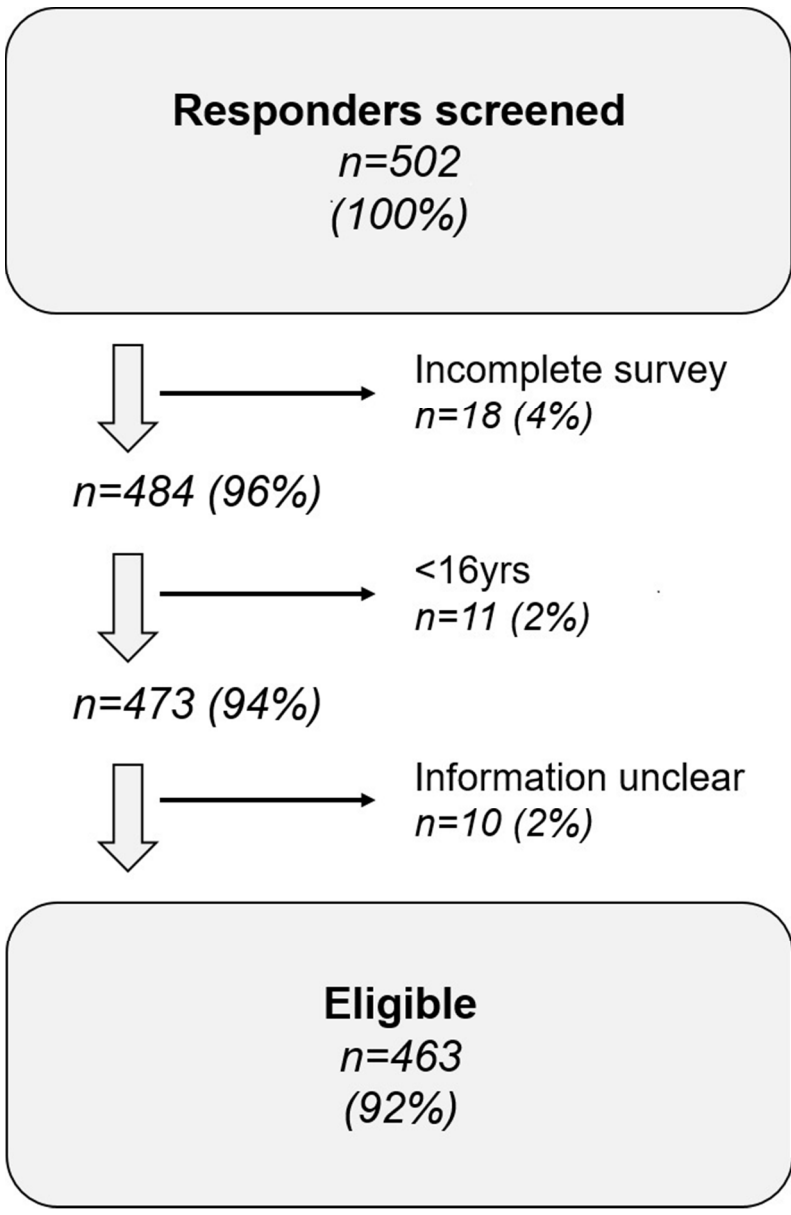


Figure 1: Baseline characteristics of eligible responders.

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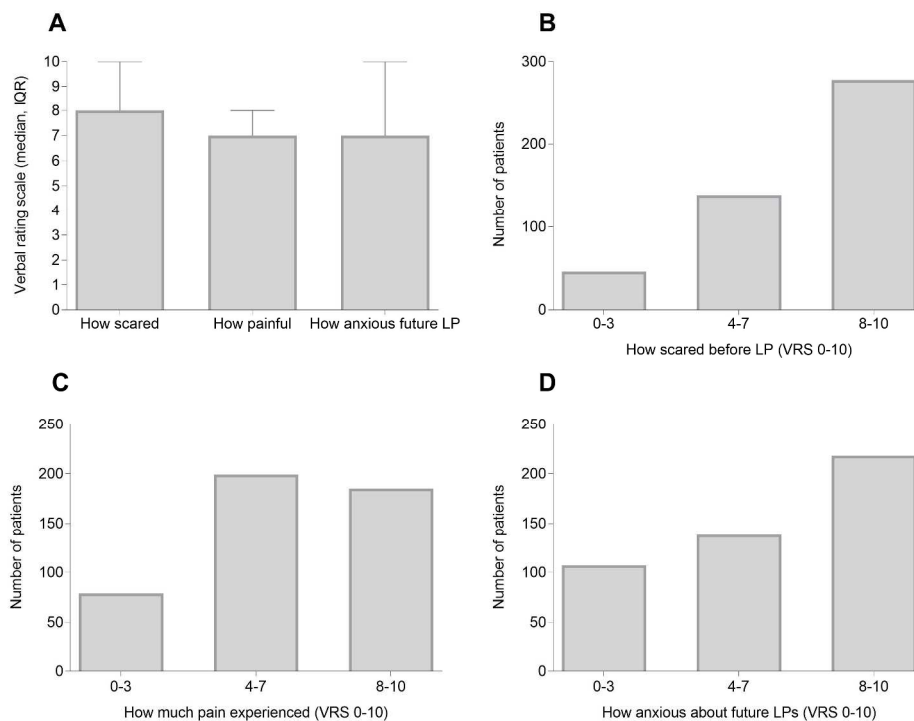


Figure 2: Patients' expectations and experience of LP. (A) Median VRS (0-10, IQR) for how scared patient was before LP, how painful the LP was and how anxious they were about future LPs. (B) Number of patients that were mildly (0-3), moderately (4-7), or very scared (8-10) before having an LP. (C) Number of patients that experienced mild (VRS 0-3), moderate (VRS 4-7) or severe (VRS 8-10) pain during the LP. (D) Number of patients that were mildly (VRS 0-3), moderately (VRS 4-7) or very anxious (VRS 8-10) about future LPs. [VRS 0=minimum and 10 maximal score].

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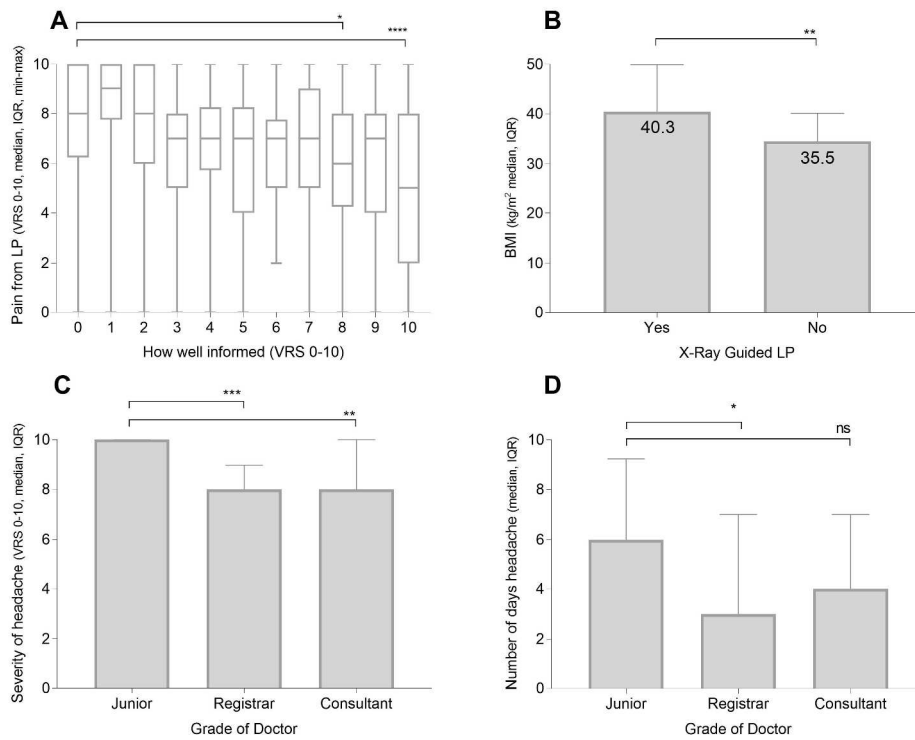


Figure 3: X-Ray guided LPs, and relationship of pre-procedural information and grade of doctor performing LP to patient experience. (A) For all patients surveyed, association between how well-informed patient was before LP, and how painful LP was (median VRS, IQR, min-max). (B) BMI (median, IQR) and association with whether patient had X-Ray guided LP. (C) Grade of doctor performing LP and duration of post-LP headache (days, median, IQR). (D) Grade of doctor performing LP and severity of post-LP headache. ns $p > 0.05$, * $p \leq 0.05$, ** $p \leq 0.01$, *** $p \leq 0.001$, [VRS 0=minimum and 10=maximal score].

280x217mm (300 x 300 DPI)

IIHUK Online Questionnaire

Demographics

1. How old were you at time of diagnostic LP?
2. What was date of your first lumbar puncture? (Do not worry if you cannot remember the exact day, but please specify month and year)
3. Since your first diagnostic LP, how many LPs have you had? (Please approximate if not sure of the exact number)
4. What is your height (metres)?
5. What is your weight (kg)?

Details of lumbar puncture

1. Was your first admission regarding your LP planned (you were sent an appointment by your doctor) or as an emergency?
2. Where in the hospital did the first LP take place? (Emergency department, Ward or In Theatre)
3. How many different doctors attempted your diagnosing LP? (i.e how many different doctors tried inserting a needle)
4. How many attempts were made to get a diagnostic LP? (An attempt being defined as a needle being inserted)
5. If the initial LP failed to get a reading did you go on to have it done in theatre under X-ray guidance?

Patient experience of lumbar puncture

1. How frightened were you about the thought of the LP before the procedure on a scale 0-10? (0 being not frightened at all, 10 being the most scared you've ever felt)
2. How well do you feel you were informed about the procedure prior to the LP on a scale 0-10? (0 being not informed, 10 being fully informed)
3. Was adequate analgesia (i.e. local anaesthetic) used in your diagnosing LP?

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4. How much pain did you experience during the LP on a scale of 0-10? (0 being pain free, 10 being worst pain ever experienced)
5. On a scale of 0-10, how anxious do you feel about having LPs in the future? (0 being not anxious, 10 being the most anxious you've ever felt)

For peer review only

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (Pg1) (b) Provide in the abstract an informative and balanced summary of what was done and what was found (Pg 3-4)
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported (Pg5)
Objectives	3	State specific objectives, including any prespecified hypotheses (Pg5)
Methods		
Study design	4	Present key elements of study design early in the paper (Pg5-6)
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection (Pg6)
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants (Pg6 & Figure 1) (b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable (Pg5-6)
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group (Pg5-6)
Bias	9	Describe any efforts to address potential sources of bias (Pg11)
Study size	10	Explain how the study size was arrived at (Pg6)
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why (Pg 6)
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (Pg6) (b) Describe any methods used to examine subgroups and interactions (Pg6) (c) Explain how missing data were addressed (Pg6 – responders with missing data excluded from study) (d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy (n/a) (e) Describe any sensitivity analyses (n/a)

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Results

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (Pg 7 & Figure 1) (b) Give reasons for non-participation at each stage (see above) (c) Consider use of a flow diagram (Figure 1)
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (Pg 7 & Table 1) (b) Indicate number of participants with missing data for each variable of interest (Pg 7) (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures (Pg7-8)
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (Pg7-8) (b) Report category boundaries when continuous variables were categorized (Pg7-8) (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period (n/a)
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses (n/a)

Discussion

Key results	18	Summarise key results with reference to study objectives (Pg 8-10)
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias (Pg11)
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence (Pg11)
Generalisability	21	Discuss the generalisability (external validity) of the study results (Pg9)

Other information

Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based (Pg2)
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*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.