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The development of patient information leaflets incorporating patient diversity considerations: Varicocele embolisation and fluoroscopy guided joint injection examinations

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ABSTRACT

Purpose: The production of patient information leaflets (PILs) for diverse patient cohorts is challenging. This study developed varicocele and fluoroscopy guided joint injection (FLGJI) procedural PILs.
Methodology: Evidence-based PILs were developed, providing radiological procedural information – preparation, explanation of interventional procedures and aftercare. PIL readability was tested via validated readability programs: Flesch Kincaid and Flesch ease reading score methods. Radiology approval of PIL(s) content was confirmed. PILs were distributed with appointment information. Patient interviews were conducted just prior to examination and by telephone, 7 days post procedure.
Results: Participants were purposely sampled (6 months): varicocele embolisation (n = 17) and FLGJI (n = 47). Overall 78.1% of all participants preferred Maltese leaflets. Varicocele embolisation patients were generally younger and a greater percentage educated to tertiary level compared to FLGJI patients. Education and age were found to be recurrent significant variables in the patient demographics and responses for both patient cohorts. Age versus education for the FLGJI cohort proved to be significant for several responses. Readability statistics identified the FLGJI leaflet as a plain English rating, the varicocele embolisation leaflet was more difficult. Patient feedback identified 'what is a varicocele?' as important to varicocele embolisation patients whereas FLGJI patients chose, 'advice about aftercare' and 'advice about pain management', highlighting differences in patients' priorities between procedures.
Conclusion: PILs provided tangible, accurate information pre and post examination. Patient involvement in achieving appropriate information informed the PILs development, which were adopted clinically. The development of tailored PILs to meet the diversity of other interventional radiology procedures is recommended.

Introduction

Exchange of information is the base of any doctor–patient relationship.[1] The general notion is that patient information leaflets (PILs) are essential for patients.[2] Cayton (2004) states that "without information there is no choice."[3] The modern patient is eager to acquire more information regarding personal health and procedures being performed.[4,6] Direct face-time between clinicians and patients is time constrained, therefore PILs can help fill in information gaps which might have been left out unintentionally in clinics, when planning diagnostic imaging options.[7] Patient leaflets also provide the patient with a tangible and accurate piece of information to refer to after consultation.[8] Once patients are in receipt of an information leaflet they process information at their pace.[9]

As interventional radiology options grow, patients are being offered more choice for treatment than there ever was before.[15–17] This is mainly attributed to innovations and the less invasive characteristic of interventional radiology that allows for high quality imaging and treatment compared to surgery, together with

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a reduction in patient hospital stays.[18] Despite over 18 different types of interventional procedures being performed in the participating clinical centre (population catchment: 430,000[19]) from 2016 onwards, many do not have tailored PILs. The demographics of the patients attending examinations varies as does the complexity of information required to be given to patients.

However, a question raised by many literature sources is whether patients really understand the material.[7,10–13] Remembering information is dependent on how information is presented to the patient.[8] The American Psychological Association[14] mentions that age brings about memory loss, additionally patients above seventy years with limited reading skills are more likely bound to have approximately two times less health and healthcare access, compared to people with adequate or higher literacy skills.[10] Schmand et al. (1997) state that two tests known as 'LASA' and 'AMSTEL', "*indicate that memory decline is most pronounced in the elderly with relatively little education.*"[5]

The aim of this study was to develop patient information for two interventional procedures performed on an out-patient basis. Variocele embolisation and FGJI procedures are performed on two different patient demographic cohorts and involve substantial differences in patient experience and aftercare. The study focused upon the importance of readability and leaflet content for the two patient cohorts, hypothesising that these factors require consideration specific to each examination. Readability testing, the patient's ability to recall PIL content and their self-reported compliance and satisfaction, in addition to radiology feedback were used as metrics for the PIL development and evaluation.

Methodology

Full ethical approval was gained from the participating clinical centre[47–49] and an ethical waiver attained from the supervising academic institution (LS-E-17-46-Vassallo-Maher). Literature was reviewed with regard to aspects of leaflet design.[22] Initial leaflet content was developed based on literature and radiology input and then tested for readability, prior to distribution to patients.

Leaflet presentation

- A simple A4 format
- The font '*Times New Roman*'[24] size 12 as the smallest font[25,50]
- 1.5 line spacing - to increase white space[50] and decrease dense paragraphs that might discourage reading[26,27]
- No text was underlined[26]
- Where possible, bullets points were included
- Sentences kept simple and short
- Medical jargon minimised

Readability testing: PIL development

'Flesch Reading Ease' and the 'Flesch-Kincaid grade level' are two validated methods used to assess readability and comprehension, these provide a high correlation with other readability scales.[23] Interpretation of the scoring applied is outlined in Table 1.

Readability statistics were not possible for the Maltese leaflets, however native Maltese speakers (n = 4) of mixed professional backgrounds and lay-reader volunteers (n = 4) determined alignment to the English leaflet, post translation, the readability status of the Maltese versions was deemed similar to the English versions. The pre and post procedure interview questions were piloted on FLGJI patients (n = 4) and varicocele embolisation patients (n = 2) in the preparatory stages of the research. The process for leaflet production is outlined in Fig. 1.

Table 1
A summary of readability scoring interpretation.

Flesch Kincaid Grade Levels		Flesch Ease Reading Score	
Grade	Reading Age	Descriptor	Score
6	11–12	Very Easy	100–90
7	12–13	Easy	90–80
8	13–14	Fairly Easy	80–70
9	14–15	Plain English	70–60
10	15–16	Fairly Difficult	60–50
11	16–17	Difficult	50–30
		Very Difficult	30–0.0

Patient sampling

Two separate patient cohorts were included in the study; varicocele procedures were scheduled weekly whilst several FLGJI procedures were completed each week. To gain maximum feedback all presenting patients who met the inclusion criteria and who were willing to participate were include over a 22 week period for varicocele embolisation procedures and a shorter period of 11 weeks for FLGJI procedures. Symmetry of these separate cohorts was not pursued.

Leaflet distribution

The Maltese and English leaflet was sent with appointment letters alongside a cover letter introducing the researcher, explaining the aims of study, and requesting participation. Patient inclusion criteria were out-patients with an ability to understand either Maltese or English and ability to read. Exclusion criteria were patients who are not able to communicate and those unable to read. This was overseen by the radiology secretary who liaised with patients and confirmed their appointments.

Patient feedback pre and post procedure

Upon arrival for their appointed procedure patients were interviewed by the researcher, (radiographer; 15 years' experience), in Maltese or English according to their preference. Interview questions were aligned to PIL sections to test understanding, recall and compliance (Table 2).

Furthermore, to test for compliance participants were contacted by telephone post procedure (n = 7 days) to ascertain whether the leaflet matched the reality of their experience, whether they adhered to the instructions of aftercare and if they needed to call their doctor in the following days after the procedure. They were finally asked if they had suggestions for the leaflet to add value to the information in the leaflet.

Data analysis

Both descriptive and inferential statistics are presented. SPSS version 25 was employed. The Chi Squared Test tested association between variables. The Friedman test was used to compare mean rating scores provided to a number of related statements.[22,23,28] The null hypothesis specifies that mean rating scores are similar and is accepted if the p value exceeds the 0.05 level of significance. Statistically significant findings were identified by a $P < 0.05$.

Results

Hospital statistics[20,21] related to the frequency of the two selected procedures, performed locally were: varicocele procedures (all Males) – n = 3 (2013); n = 7 (2014); n = 14 (2015); n = 19