

Efficacy and quality of informed consent for Dacryocystorhinostomy—a prospective study

Abstract

Informed consent is an integral part of good clinical practice; it is a legal and ethical principle, enabling patients to make decisions about their medical and surgical care in an autonomous and self-determined way.¹ For consent to be valid, it must be given freely and voluntarily by a capacitated patient who has been sufficiently informed about the consequences of their choices.^{2,3} In clinical practice, the actual journey in obtaining valid consent may be a long one, especially when consenting for surgical procedures. In its completeness, the consenting process comprises a patient focussed discussion on the diagnosis, prognosis and issues that require intervention, the nature and benefits of the intervention, the associated risks, the available alternatives and consequences of no intervention, and opportunities for the patient to ask further questions.^{4,5} The patient can be given decision aids (patient information leaflets/web/videos), encouraged to involve people in the processing of information (spouse/relative/friend) and encouraged to delay formal consent after a period of time for consideration.⁵ Additionally, the clinician tailors their approach depending on the degree of patient knowledge and the complexity of the procedure, re-checking whether the patient has understood adequately to make a decision.⁴ The discussion that has occurred and the patient's decision must be documented in the medical records, along with a standard signed consent form.⁶

Keywords: surgery, dacryocystorhinostomy, ophthalmology

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Introduction

To date, consent for complex ocular procedures has not received much attention in the literature. As a specialty, ophthalmology surrenders to the 'treadmill' efficiency of pooled lists, assigned assessments and generic patient information sheets.⁷ There is an assumption that valid consent has been gained when patients may still be uninformed. Furthermore, patients may report high levels of satisfaction, yet remain to have poor levels of understanding.⁸ Patient retention of operation risks is poor and the capacity to provide fully informed consent is influenced by the patients level of education, literacy and language competency.⁹⁻¹¹ The anatomy of the lacrimal system and potential for surgery is a difficult concept for patients to perceive, especially without pictorial or comprehensive written material devoid of medical jargon. Considering all these factors, it may be likely that the process we deem as valid consent is actually an uninformed one. To our knowledge no prior studies have looked at objective improvement in patient recollection and understanding during informed consent for dacryocystorhinostomy (DCR). In our survey, we aimed to evaluate the effectiveness of our current standard consenting process for dacryocystorhinostomy (DCR) at increasing understanding and comprehension in a competent patient in a specialist ophthalmology centre in London.

Methods

A prospective study was carried out on patients undergoing DCR over a period of 6 months. Patients who met the inclusion criteria were approached (Table 1). At initial consultation and listing for surgery, patients encountered a verbal discussion with an ophthalmology fellow or consultant on the risks, benefits and expectations of DCR surgery as per normal procedure and were given a leaflet containing the same information to take away and read. On the day of surgery, participants who agreed to take part in the study were asked questions

from an 8-item questionnaire. The questions aimed to establish patient understanding of indications, details of the procedure and details of associated risks ([Appendix 1](#)). Patients were then permitted to continue with the usual consenting process which involved signing a consent form to indicate completion of fully informed consent. At 2 weeks post DCR, patients were called via telephone to complete the same questionnaire with additional questions on overall satisfaction of the consenting process, on level of formal education and on other factors that may have influenced their understanding of the procedure (presence of a family member during the consenting process, encounter with someone who has had the same operation before and whether they used the internet to research the procedure themselves) ([Appendix 2](#)). Efficacy of consent was measured by percentage increase in correct responses and mean number of risks recalled pre and post informed consent. Overall satisfaction of the consenting process was measured through a score out of 5 (1=poor, 5=excellent).

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Receiving endonasal DCR surgery under GA	Unable to understand English language
18 years or above	Lack mental capacity
Able to speak or understand English language	

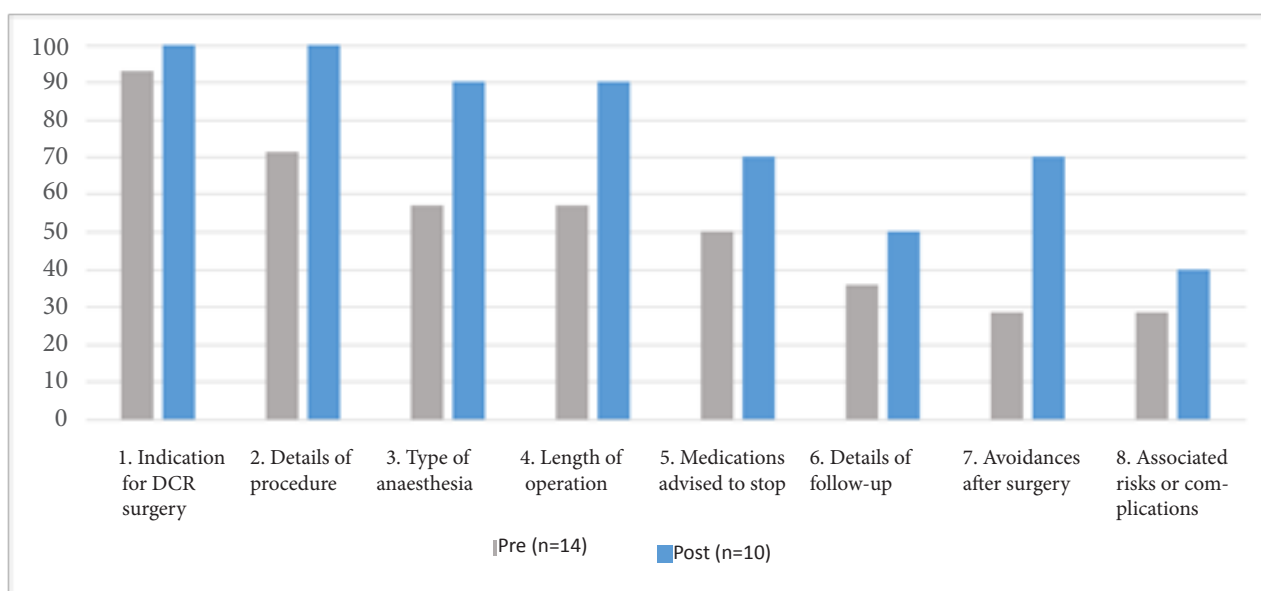
Results

A total of 14 patients agreed to take part in the study and met the inclusion criteria (6 women and 8 men). All patients completed the initial 8-item pre DCR questionnaire. The mean age of participants was 69. Only 10 patients responded to complete the post DCR questionnaire. Out of these patients, 4 patients had received higher

level education, 5 received lower level education and 1 patient did not disclose. None of the patients reported looking up the procedure on the internet. 4 patients had a family member present during the consenting process whilst the others were alone. 2 patients had encountered someone who had had a DCR operation before and conversed with them. No patients had used the internet to research the procedure. The mean overall satisfaction score for the consenting process at our unit was 3.9 out of 5.8 patients gave a satisfaction score of 4 and 5.2 patients gave a satisfaction score out of 1. One of these patients made no comments about why they gave this score and the second patient felt they had a lack of explanation and the surgical experience was not as bad as she had expected. Despite one patient having the same symptoms as before surgery, they gave a satisfaction score of 5.

Prior to completing informed consent, 93% of patients gave correct response for indication and 71% of patients gave correct responses for details of the procedure (Graph 1). After fully informed consent, 100% of patients gave correct responses for indication and details of the procedure. Prior to completing informed consent, 57% of patients answered correctly about type of anaesthesia. After fully informed

consent, correct responses for type of anaesthesia increased to 90%. Correct response by patients for length of surgery time was 57% prior and 90% post completion of fully informed consent. 50% of patients knew which medications to stop before the operation but this increased to 70% after being fully consented. With regards to details on follow-up, correct responses increased by 14.3% and for avoidances after surgery, correct responses increased by 41.7% (Graph 2). For recall of risks, correct responses increased by 11.7% but ultimately only 40% of patients were able to recall one or more risks or complications after apparent fully informed consent. Out of these patients, an average of 1.75 risks was recalled out of a possible 8 risks that were routinely mentioned during consent. Only 1 of these patients had both a family member present during the consent process and had known someone who had had this surgery before. The most common risk factor recalled was bleeding (Table 2). In the further comments section, one patient stated that they were not aware they were having a silicon tube placed and because of this lack of knowledge attended emergency services. This patient gave an overall satisfaction score of 4 out of 5. Another patient stated that they received a lack of explanation and gave a satisfaction score of 1 out of 5. The rest of the patients had no further comments.



Graph 1 Percentage of correct responses before and after fully informed consent (%).

Table 2 Number of each risk recalled by 10 patients

Infection	2
Bleeding / bruising / nose bleeds	4
Damage to other structures	0
Tubes falling out	1
Failure / blockage	0
Need for further procedure	0
Scarring	1
Allergy	0
Congested nose	0

Discussion

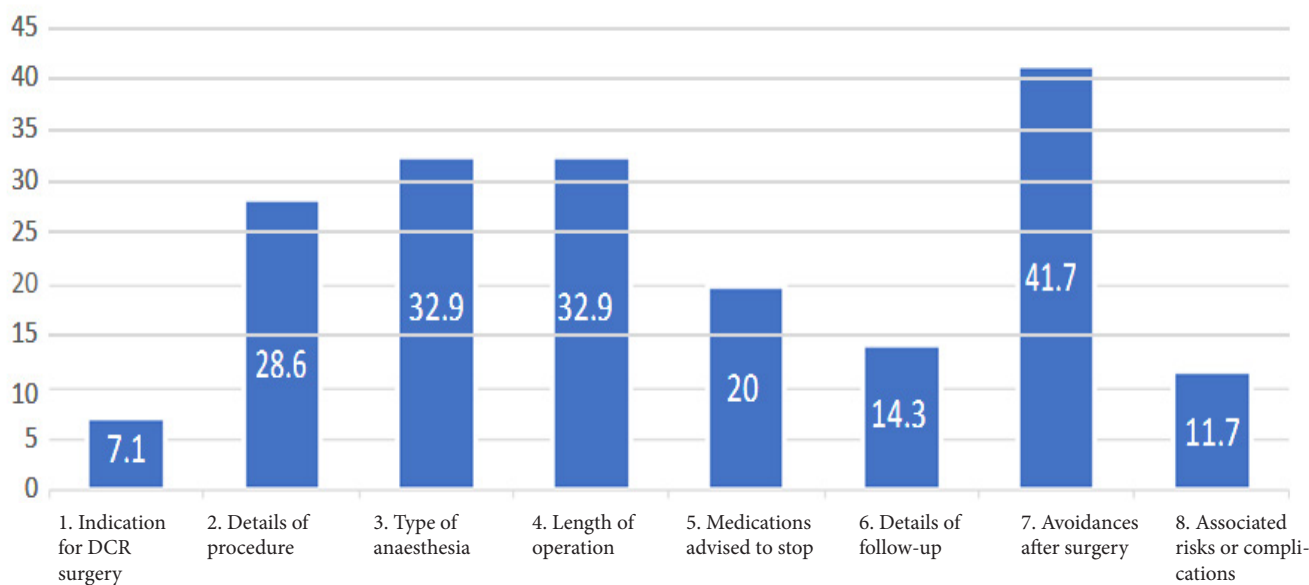
Informed consent is a legal and ethical process, allowing patients to make autonomous decisions when it comes to the nature, risks and benefits of surgery. In view of the complexity and intricate anatomy of DCR surgery, we wanted to evaluate the validity of our current consenting process in our cohort of patients at our specialist centre in London. Retention of surgical indications, procedure details and especially recall of risks have been used in previous studies to assess consent.^{10,12,13} We used similar parameters in our study to objectively assess informed consent, as well as patient satisfaction of the consenting process. Every patient had a standard discussion with an appropriate clinician and opportunity to ask questions, receiving the same hospital information leaflet at their initial consultation. There were approximately equal numbers of patients with high level and low-level education; no patients looked up the procedure over the

internet. These factors meant less confounder when interpreting the results in view that level of education and interactive media leads to improved understanding of surgery.⁹

Most patients stated they were satisfied with the consenting process and made no comments. However, two patients gave poor satisfaction scores with one patient stating a lack of explanation. Of note, both these patients were not able to recall any risks or

complications. There is evidence to suggest that patients' recollection of the consenting process conflicts with that of physicians'.^{9,14} Our own results demonstrated that despite similar information being given to all patients, some patients felt the discussion inadequate. Reconfirmation or tailoring of the discussion to improve patient retention and ultimately satisfaction should be re-emphasized at our centre in view of these unsatisfactory results.

1. Indication for DCR surgery



Graph 2 Percentage increase in correct responses (%).

In general, there was a downward trend in number of correct responses from question 1 to 8. This supports the notion of patient inadequacy of recalling information about surgical procedures as more information is given during the consultation. This may be especially apparent in consenting for DCR surgery in view of its complexity and ability to comprehend the anatomy involved. Correct responses were mainly for indication of surgery and details of the procedure itself. Topics usually addressed at the end of the consultation such as details of follow-up, avoidances after surgery and risks of surgery tended to give lower numbers of correct responses. It is therefore important to note that during the consenting process for this complex procedure, cumulative information will need further consolidation by the patient at a separate time. Unsurprisingly, studies show that repetition, even more than twice, of the consent information is required for full understanding and is not achieved through one reiteration or even two reiterations alone.^{15,16}

After complete informed consent, percentage of correct responses increased across all 8 questions demonstrating effectiveness in our current consent process. Informed consent was effective in increasing patient understanding of details of anaesthesia, length of operation and avoidances after surgery. These areas may have been particularly salient for patients from a practical perspective and therefore garner more recollection. Knowledge of surgical indications and procedure details remained high throughout informed consent in the majority of patients. However, DCR patients were poor at remembering complications. Poor recall of risks may demonstrate the difficult nature of visualizing the anatomy of the nasolacrimal duct and its

purpose. It may also be because the discussion of these is approached towards the latter part of the consultation when their attentiveness to the information waned. Nonetheless, our findings are in-keeping with other studies showing poor patient retention of operation risks.¹⁷ One of the chief reasons in the literature for litigation against surgeons is lack of informed consent, primarily in relation to complications related to surgery.¹⁰ We have demonstrated an important area where patient understanding is unaccomplished by our current methods.

There is scope for improving recollection of complications at our centre and several studies have used reinforcement methods of information delivery to do this. In view of the difficult anatomy involved, a pictographic or visual aid may enhance patient understanding of DCR risks ([Appendix 3](#)). However, studies assessing effects of improving recall with visual aids or multimedia show equivocal results with some studies showing their effectiveness whilst others demonstrating no improvement in recalling risks.^{9,10,12,18} This may be procedural dependent and a comparison study between enhanced visual aids and generic patient information leaflets will be needed to assess the effectiveness of visual aids in improving recollection in DCR patients. The main limitation of our study is the small sample size. Due to the observational nature of the study, it is difficult to calculate an ideal sample size. However, studies looking at recall in consent tended to have higher sample sizes than our study. The patient satisfaction scoring was also not validated but it appeared to indicate that patients were generally pleased with the overall informed consent process. Patients underwent the second questionnaire after the DCR procedure itself and therefore confirmation of informed consent

was subject to recall bias. Subjection of the questionnaire on the day of surgery prior to the operation would have also been invalid due to inefficient time elapsed to test short to intermediate-term knowledge suggestive that the consenting process had a real impact on patients' understanding of the DCR surgery they were undergoing.

Conclusion

To conclude, achieving informed consent is a complex process and should be a process rather than a single or even dual event. Our findings can be used to further elucidate mechanisms to improve patient understanding and consent in DCR surgery.

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Conflicts of interest

Author declares that there are no conflicts of interest.

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