International Journal of Science and Research (IJSR)
ISSN: 2319-7064
SJIF (2022): 7.942

How to Improve Informed Consent Process in Elective Laparoscopic Cholecystectomies?

Dr. Chandan S. A [1], Dr. Rehana Begum[2]

[1]Assistant Professor, Department of General Surgery, BGS Global Institute of Medical Sciences, Bengaluru, India

[2]Post Graduate, Department of General Surgery, BGS Global Institute of Medical Sciences, Bengaluru, India

Abstract: ***Background: The current time requires clinicians to improve the health education we provide in clinics. Individuals undergoing major surgery should be well informed and provided with enough time to make a decision. Methods: This is a closed loop audit aimed at improving the informed consent process for day case laparoscopic cholecystectomy by audio - visual aids in clinics. We asked fifty patients attending clinics for consideration for a day case laparoscopic cholecystectomy what they thought of the standard informed consent by filling a simple questionnaire after a clinic visit. After reviewing the results, we realised the process of consenting needs to improve. We then improved the informed consent procedure by adding an informative video for clinics and developed a new information leaflet. Thirty - five patients gave their feedback on the new consenting process by filling in a simple questionnaire at the end of their clinic consultation. Results: A survey assessed our current consenting process. Out of the 50 returned questionnaires, thirteen patients did not remember any of the conversation in clinic. Five patients were consented on the day of the surgery. In conclusion, individuals agreed audio - visual information would be beneficial for the consenting procedure in clinic. We organised a new information leaflet to improve our informed consent procedure. Information included was about the perioperative journey and specific anatomy and risks of a laparoscopic cholecystectomy. We received excellent feedback from 35 patients. We have applied this change to the current day case practice. Conclusion: Audio - visual aids help in providing patients with good quality information for a well - informed mutual agreement about major surgical procedures. The author finds audio visual aids are useful for discussing major surgical procedures in the clinic and does not affect the amount of time spent with each patient.***

Keywords: Informed consent; Laparoscopic cholecystectomy; Audio - visual aids, Written informed consent, quality improvement.

1. Introduction

Gallbladder surgery has evolved through a series of interesting events over more than acentury [(1).] The first laparoscopic cholecystectomy was performed by Professor Dr Med Erich Mühe of Böblingen, Germany on September 12, 1985. He eventually received recognition of his work in 1995 with 'The German Surgical Society Anniversary Award' [(2).] He can be given credit for inventing numerous instruments used in a laparoscopic cholecystectomy. Despite it being one of the commonest day case procedures, patients often are referred from clinicians with limited surgical experience of the procedure. This is where audio - visual education in clinics can be beneficial [(3).] We made improvements in consenting with audio - visual aids in the form of a video, literature and signing a written consent in clinic. It is common knowledge that more audio - visual aids improve health education and understanding. Informed consent is the mutual agreement between the clinician and the individual for a surgical procedure after thorough discussion of the options, the risks and the perioperative pathway of surgery. We know that despite thousands of such day case procedures progress uneventfully, complications still happen.

2. Materials and Methods

Source of data: patients who underwent elective laparoscopic cholecystectomy in BGS Global Institute Of medical sciences and hospital.

Methods of data collection:
Study design: observational
Study period: January 2021 - January 2023
Place of study: BGS Global Institute of Medical Sciences and Hospital.
Sample size 50 (25 per group).

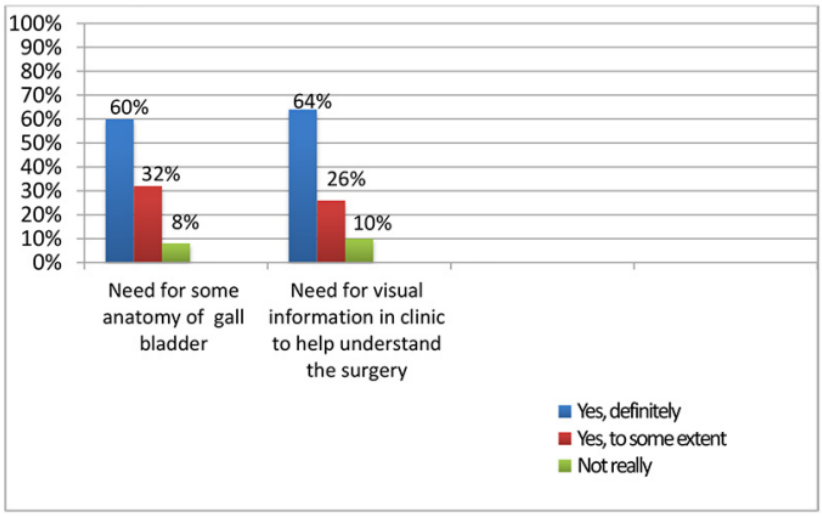
Inclusion criteria:
Patients aged more than 18 years undergoing elective laparoscopic cholecystectomy.

Exclusion criteria:
Emergency procedures
Medical background patients.

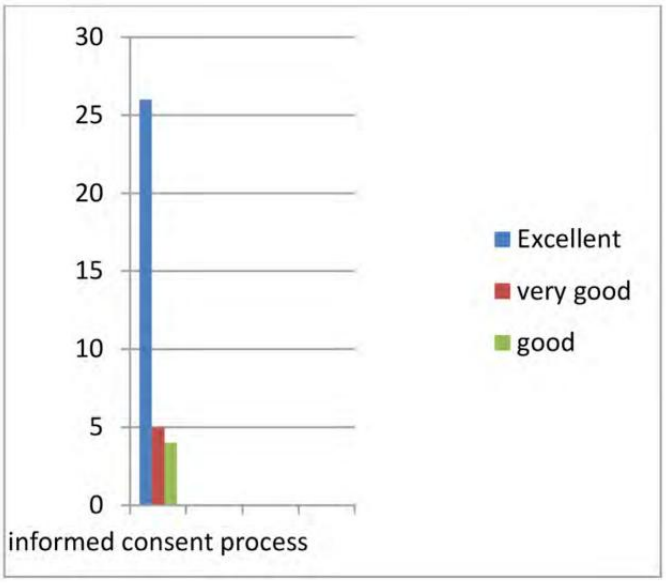
3. Results

The results revealed that all the patients were informed of the options, risks and benefits of the procedure at clinic appointment. Patients were provided information leaflets in the clinic.32 patients in the clinic out of the 50 received a copy of the signed consent form. Thirteen patients did not remember the conversation in the clinic. Five patients were consented on the day of surgery. Most individuals agreed strongly that audiovisual aids would help in understanding the anatomy and the complex hepatobiliary risks from a laparoscopic cholecystectomy.

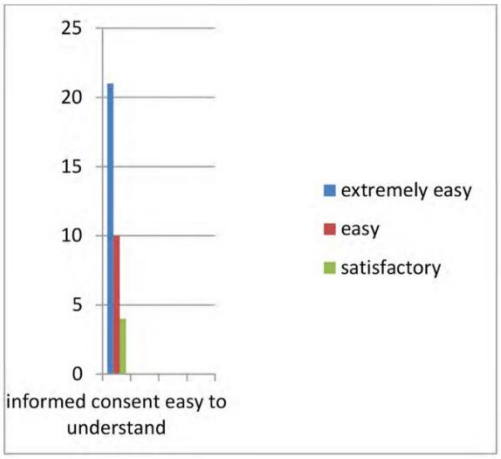
Graph 1: survey of patients attending clinic for consideration of surgery>



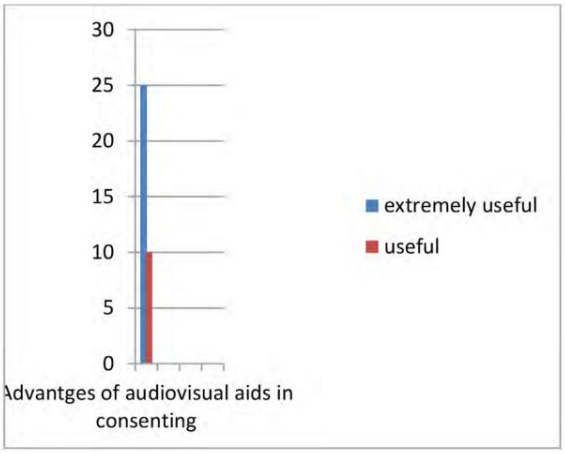
Graph 2: assessment of informed consent process.



Graph 3: Is the informed consent easy to understand?



Graph 4: Are audio-visual aids advantageous in consenting.



4. Discussion

The GMC guidance emphasises that you should, 'share information in a way the patient can understand and, wherever possible, in a place and at a time when they are best able to understand and retain it' (GMC 2008).

Elements of an informed consent form:

An effective and ethically valid informed consent needs to consider preconditions like competence on part of the patient to understand and make a decision and the voluntariness in

deciding, free from controlling influence, including coercion, persuasion or manipulation.

The elements essential for information provided should include not only thorough disclosure of material information to the patient, including the alternatives, risks & benefits of treatment but also the physician's recommendation of a plan.

The consent elements should include the decision in favour of a plan by the patient and authorization given by the patient of the chosen plan. [4]

Health education and its retention can improve with numerous techniques like literature about the procedure, 'repeat back' to assess retention of knowledge, second clinic discussion and audio - visual aids.

Repeating the information provided in any form can be useful to make an informed decision. In a multicentre randomised controlled trial (RCT), individuals in the control group were consented the standard way and the experimental group assessed with 'repeat back' including standard informed consent. It was concluded after 575 patients assessed by a questionnaire that individuals benefitting from repeat back took longer to consent but had much improved comprehension of the procedure. [5]
Thirty - seven individuals were consented in the standard way whereas 33 individuals had a graphically formatted, easy to understand consent form. Assessment questionnaires were filled in by the individuals showing improved comprehension of the surgical procedure and the risks. [6]

The use of multimedia including video and graphic illustrations aid in improving health education and the tools can repeated in the comfort of the individual's own living room to reinforce the already acquired knowledge. [7, 8]

Contents of the informed consent need to include the most common and the most serious of complications, however consensus between even groups of surgeons can be difficult to attain because of a variety individual opinion and experience. There have been attempts to bridge this difficulty by applying techniques like the Modified Delphi Technique to achieve consensus and to optimise the information provided. Despite our efforts to improve the process, we do acknowledge some weaknesses. [9.10]

5. Conclusion

Informed consent is an opportunity to discuss the clinical management between the clinician and the individual undergoing an intervention rather than an exercise to fulfil legal requirements. To maintain this sacred bond between the patient and clinician, an informed consent that provides adequate knowledge and meaningful understanding should be of utmost priority. Multimedia can be utilised to improve this process.

References

[1] Sparkman RS.1982.100th Anniversary of the First Cholecystectomy: A Reprinting of the 50th Anniversary Article From the Archives of Surgery, July 1932. Arch Surg. doi: 10.1001/archsurg.1982.01380360001001.
[2] Reynolds W.2001. The First Laparoscopic Cholecystectomy. J Soc Laparoendosc Surg
[3] Clarke MG, Wheatley T, Hill M, Werrett G, Sanders G.2011. An Effective Approach to Improving Day Case Rates following Laparoscopic Cholecystectomy. Minim Invasive Surg. doi: 10.1155/2011/564587
[4] Beauchamp TL.2011. Informed consent: Its history, meaning, and present challenges. Cambridge Healthc Ethics. doi: 10.1017/S0963180111000259.
[5] Fink AS, Prochazka A V., Henderson WG, Bartenfeld D, Nyirenda C, Webb A, Berger DH, Itani K, Whitehill T, Edwards J, et al.2010. Enhancement of surgical informed consent by addition of repeat back: A multicenter, randomized controlled clinical trial. Ann Surg. doi: 10.1097/SLA.0b013e3181e3ec6.
[6] Borello A, Ferrarese A, Passera R, Surace A, Marola S, Buccelli C, Niola M, Di Lorenzo P, Amato M, Di Domenico L, et al.2016. Use of a simplified consent form to facilitate patient understanding of informed consent for laparoscopic cholecystectomy. Open Med. doi: 10.1515/med - 2016 - 0092.
[7] Bollschweiler E, Hölscher AH, Obliers R.2009. Improving Informed Consent of Surgical Patients Using a Multimedia - Based Program? Ann Surg. doi: 10.1097/sla.0b013e31819ac459.
[8] Wilhelm D, Gillen S, Wirnhier H, Kranzfelder M, Schneider A, Schmidt A, Friess H, Feussner H.2009. Extended preoperative patient education using a multimedia DVD - impact on patients receiving a laparoscopic cholecystectomy: A randomised controlled trial. Langenbeck's Arch Surg. doi: 10.1007/s00423 - 008 - 0460 - x.
[9] Tipotsch - Maca SM, Varsits RM, Ginzel C, Vecsei - Marlovits P V.2016. Effect of a multimedia - assisted informed consent procedure on the information gain, satisfaction, and anxiety of cataract surgery patients. J Cataract Refract Surg. doi: 10.1016/j. jcrs.2015.08.019.
[10] Lin YK, Chen CW, Lee WC, Lin TY, Kuo LC, Lin CJ, Shi L, Tien YC, Cheng YC.2017. Development and pilot testing of an informed consent video for patients with limb trauma prior to debridement surgery using a modified Delphi technique. BMC Med Ethics. doi: 10.1186/s12910 - 017 - 0228 - 3