Informed consent practices in oral and maxillofacial surgery setups — an audit report

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Abstract

Objective: To evaluate the existing practices of obtaining and documenting informed consent in cases of oral and maxillofacial surgery.

Methods: The cross-sectional study was conducted from April to June 2017 at the Oral and Maxillofacial Surgery departments of five teaching hospitals of Rawalpindi and Islamabad, Pakistan, and comprised patients who underwent surgery under general anaesthesia. Data was collected using questionnaire-based interviews a day after the surgery in each case regarding multiple aspects of the informed consent practices. Data was analysed using SPSS 21.

Results: Of the 100 patients, 58(58%) were males and 42(42%) were females, while 81(81%) were adults aged >18 years. In 42(42%) cases, the consent document was signed by the patient, and by a relative in 38(38%) cases. In the remaining 20(20%) cases, only verbal consent was taken. In 54(54%) cases nursing staff and in 46(46%) cases residents took the consent. Most patients were informed about nature of their disease 87(87%), proposed treatment 86(86%) and type of anaesthesia 100(100%). Fewer patients were informed about any alternative treatments 38(38%), and possible complications of the surgery 51(51%) or anaesthesia 26(26%). Overall, 44(44%) patients did not fully understand the written information, and 23(23%) said they were encouraged to ask questions.

Conclusion: The quality of informed consent practices was found to be sub-optimal in oral and maxillofacial surgery setups.

Keywords: Maxillofacial surgery, Informed consent. (JPMA 71: 1197; 2021)

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Introduction

The specialty of Oral and Maxillofacial Surgery (OMFS) deals with the diagnosis and surgical management of diseases and disorders affecting mouth, jaw bones and face.[1] As such, surgery could affect both form (appearance) and function (breathing, chewing, swallowing, talking etc.). If deranged, they may have psychosocial implications. It is therefore necessary to inform patients undergoing OMFS about diagnosis of the condition, treatment options and their benefits as well as possible complications. The patients must understand all the information and make an educated choice about the best course of action for themselves. This process of educating the patients and seeking their agreement for the proposed management plan is called informed consent (IC) and is a significant part of the overall patient management.[2]

Properly designed, administered and documented IC satisfies both ethical as well as legal aspects of standard medical practice. Several studies have, however, shown inadequacies in IC practices in many surgical subspecialties.[3-6] Such inadequacies could not only lead to lack of patient satisfaction, but also have medico-legal consequences.[7-10]

The current study was planned to evaluate the existing practices of obtaining and documenting IC in OMFS setups.

Patients and Methods

The cross-sectional study was conducted from April to June 2017 at OMFS departments of five teaching hospitals of Rawalpindi and Islamabad, Pakistan. These included the Armed Forces Institute of Dentistry (AFID), Foundation University College of Dentistry (FUCD), Islamabad Medical and Dental College (IMDC), Islamic International Dental College (IIDC) and Pakistan Institute of Medical Sciences (PIMS). Approval was obtained from the ethics review boards of all the institutions. Patients regardless of age and gender who had undergone surgery under general anaesthesia (GA) were included. Data was collected using questionnaire-based semi-structured interviews conducted on the day after the surgery when the patient had fully recovered from the effects of anaesthesia, were comfortable and willing to participate. Those not feeling well because of discomfort

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related to maxillo-mandibular fixation, dressings, tubes, or not willing to participate due to any other reason were excluded.

The 20-item questionnaire was specifically designed and was pre-tested on 10 patients. It was used in the current study after it was modified appropriately in the light of the pilot study. The interviews were conducted by OMFS residents who were first trained for the purpose. The residents explained the questions to the subjects and, where required, provided additional information.

Data was uploaded on Excel sheet and analysed using SPSS 21. Descriptive statistics were used to determine frequencies and percentages of the variables.

Results

Of the 100 patients, 58(58%) were males and 42(42%) were females, while 81(81%) were adults aged >18 years (Table-1).

In 42(42%) cases, the consent document was signed by the patient, and by a relative in 38(38%) cases. In the remaining 20(20%) cases, only verbal consent was taken. In 54(54%) cases nursing staff and in 46(46%) cases residents took the consent (Table-2).

Most patients were informed about nature of their disease 87(87%), proposed treatment 86(86%) and type of anaesthesia 100(100%). Fewer patients were informed about any alternative treatments 38(38%), and possible complications of the surgery 51(51%) or anaesthesia 26(26%) (Table-3).

Overall, 44(44%) patients did not fully understand the written information, and 23(23%) said they were encouraged to ask questions. Despite the lack of understanding, 78(78%) patients said they were satisfied with the IC process.

Table-1: Demographic characteristics.

Demographics		Count
Age Distribution	Child	19
(Child = <18 Years)	Adult	81
Gender of Patient	Male	58
	Female	42
Educational Level	Nil	8
	School	39
	College	33
	University	20
Operated For	Dentoalveolar	10
	Trauma	42
	Cyst / Tumour	16
	TMJ	7
	Infections	7
	Orthognathic	8
	Salivary Glands	4
	Cleft Lip/Palate	6

Table-2: Pattern of taking consent.

How was the consent taken		Count
How was the consent Obtained?	Verbal	20
	Written	80
Who obtained the Consent?	Surgeon	0
	Resident	46
	Nurse	54
Who signed the consent document?	Patient	42
	Relative	38
	Verbal only	20
When was the consent obtained?	Day before Surgery	28
	Morning of Surgery	46
	Just before Surgery	22
	After Surgery	2
Did you understand the verbal information?	No	13
	Yes	86
Did you carefully read the consent document?	No	49
	Yes	51
Did you understand all the written information?	No	44

Table-3: Components of the surgical informed consent.

Components of Consent		Count
Was nature of disease explained?	No	10
	Yes	87
	Not Sure	2
Was the proposed treatment discussed?	No	14
	Yes	86
	Not Sure	0
Alternative treatment options discussed?	No	62
	Yes	38
	Not sure	0
Risks of the proposed Treatment discussed?	No	43
	Yes	51
	Not sure	5
Type of anaesthesia discussed?	No	0
	Yes	100
	Not sure	0
Risks of Anaesthesia discussed?	No	74
	Yes	26
	Not sure	0
Were you encouraged to ask questions?	No	77
	Yes	23

Discussion

The findings showed inadequacies in the documentation of IC in OMFS cases. Despite the fact that only 19% patients were <18 years, only 42% of the consent documents were signed by the patients themselves. In

38% cases, parents, siblings or other relatives signed the document on behalf of the patients. Other studies also found that in many cases relative and other attendants signed the consent document.[10,11]

In 20% cases, verbal consent was presumed to have been taken as the patient could not recall if they had singed any IC document. A study reported that patients receiving verbal information remain less well-informed compared to those receiving written information.[12]

Either nursing staff or residents were involved in taking the consent in the current study. None of the operating surgeons were actively involved in the consent process. Other studies have reported similar findings.[4,13,14] This is in contrast to best practices in the developed world where senior surgeon takes the consent[15] which ensures that the patient is adequately informed, and, with their knowledge and experience, the surgeons can answer questions of the patient or their relatives regarding any alternative treatment options and why the proposed treatment is preferred over the other alternatives. Timing of the consent process is another very significant consideration. Allowing the patient time to understand and carefully consider the information provided requires that the consent process takes place well before the actual surgical procedure. In 22% of patients in the current study, the IC document was signed just before the surgery. A study reported similar finding.[16] Also, it has been suggested[16] that patients receiving information just before surgery may consent under duress to proceed as all arrangements for surgery have already been made.

About half of those who signed the consent document, did not read it carefully in the current study which is in line with literature.[17]

Despite the shortcomings, majority of the patients in the current study expressed satisfaction with the IC process. The finding is in agreement with an earlier study.[14]

Conclusion

The quality of IC was found to be suboptimal in OMFS setups and patients remained less well-informed. Both surgeons and patients need extensive education and training in the significance, process and conduct of IC documentation.

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References

1. Hupp JR, Ellis E, Tucker MR. Contemporary oral and maxillofacial surgery. St. Louis, MO: Mosby Elsevier, 2014
2. Leclercq WK, Keulers BJ, Scheltinga MR, Spauwen PH, van der Wilt GJ. A review of surgical informed consent: past, present, and future. A quest to help patients make better decisions. World J Surg. 2010; 34:1406-15.
3. Brezis M, Israel S, Birenshtock WA, Pogoda P, Sharon A, Tauber R. Quality of informed consent for invasive procedures Int J Qual Health Care. 2008; 20:352-7.
4. Ochieng J, Ibingira C, Buwembo B, Munabi I. Informed consent practices for surgical care at university teaching hospitals: a case in a low resource setting. BMC Med Ethics. 2014; 15:40.
5. Leclercq WKG, Keulers B, Houterman S, Veerman M, Legemaata J, Scheltinga MR. A survey of the current practice of the informed consent process in general surgery in the Netherlands. Patient Saf Surg. 2013; 7:4.
6. Chima SC. Evaluating the quality of informed consent and contemporary clinical practices by medical doctors in South Africa: An empirical study. BMC Med Ethics. 2013; 14:S3.
7. Armstrong AP, Cole AA, Page RE. Informed consent: are we doing enough? Br J Plast Surg.1997; 50:637-40.
8. General Medical Council (UK). Seeking Patients Consent: The Ethical considerations. London: GMC, [Online] 1998 [Cited 2020 January 03]. Available from: URL: http://www.gmcuk.org/guidance/library/consent.asp
9. Skene L, Smallwood R. Informed consent: lessons from Australia. BMJ. 2002; 324:39-41.
10. Teuten B, Taylor D. "Don't worry my good man--you won't understand our medical talk": consent to treatment today. Br J Ophthalmol. 2001; 85:894-6.
11. Jafarey AM, Farooqui A. Informed consent in the Pakistani milieu: the physician's perspective. J Med Ethics. 2005; 31:93-6.
12. Siddiqui FG, Shaikh JM, Memon MM. An audit of informed consent in surgical patients at a university hospital. J Ayub Med Coll. 2010; 22:133-5.
13. Armstrong AP, Cole AA, Page RE. Informed consent: are we doing enough? Br J Plast Surg.1997; 50:637-40.
14. Ashraf B, Tasnim N, Saaiq M, Zaman K. Informed consent for surgery: do our current practices conform to the accepted standards? J Coll Physicians Surg Pak. 2014; 24:775-7.
15. Jawaid M, Farhan M, Masood Z, Husnain SM. Preoperative informed consent: is it truly informed? Iran J Pub health. 2012; 41:25-30.
16. Anderson OA, Wearne IM. Informed consent for elective surgery-what is best practice? J R Soc Med. 2007; 100:97-100.
17. Agozzino E, Borrelli S, Cancellieri M, Carfora FM, Di Lorenzo T, Attena F. Does written informed consent adequately inform surgical patients? A cross sectional study. BMC Med Ethics. 2019; 20:1.