A REVIEW OF LITERATURE REGARDING MEDICO-LEGAL ASPECTS IN GYNAECOLOGIC ENDOscopy: DO PATIENTS’ DEMANDS AND DOCTORS’ SERVICES MEET?

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Abstract

The endoscopic surgery, despite its very sophisticated aspect and appearance of advanced technology, is still another way of doing surgery. The patients and sometimes even specialists are tempted to promote the technique as “safe” and “almost non-invasive”, disregarding the minor pitfalls and complications related to it. In gynaecology, this aspect is even more frequent as the pre-concept of “minor surgery” imposed to some interventions from this specialty find a favourable psychology in some women. Training and certification on gynaecological endoscopic surgery will play a pivotal role in the near future of medico-legal problems. Surgeons who underwent a recognizable education and testing, defending their position for a mistake have a strong argumentation that were eligible and able to perform a complicated operation. Whether Gynaecological Societies like the European Society for gynaecologic Endoscopy (ESGE) and the European Society for Human Reproduction and Embriology (ESHRE) will be called to the court to defend and justify their certified surgeon members’ abilities and performance is debatable. We analyze data of the literature, and make some considerations which unveil the miscommunication that should be focused by the gynaecologist in approaching this domain.

Keywords: gynaecologic endoscopy, patients satisfaction, medical ethics

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Introduction

When Palmer performed his first laparoscopic surgeries more than 60 years ago, he already saw in this method the revolution that would lead to major changes in gynaecologic surgery. After that, however, for many years, endoscopic surgery remained more familiar to general surgeons, and only in the last 40 years, through dedicated surgeons like K. Semm, M. Bruhat, C. Sutton, etc, the gynaecologists have discovered the benefits of this technique.

The patients were exposed to the new technical developments of recent years, which brought computer technology, Internet, more performant medical devices, and translated them to the surgeons in front of them. Media and fast information that characterise our times have also contributed to this rapid acceptance.

But unlike other new technologies, in surgery new methods depend on the convergence of different aspects: adequate and consistent technology endowment, learning curve, adaptation of surgical procedures to the new techniques specificity, medical education of patients. This could create a gap between what surgeons perform and what patients expect. For this reason, we analyzed the data in literature that deals with the communication between patients and gynaecologists, to see if changes could arise in the perception of both partners towards better endoscopic surgery.

What do women expect from their gynaecologic endoscopy specialist?

In 2008, the American Association of gynaecologic Laparoscopist (AAGL) conducted a survey over 526 women aged over 18 that were asked about their awareness about endoscopic gynaecologic surgery, also called “minimally invasive surgery”. Women expect their gynaecologist to offer them treatment options with the least amount of pain (98%) and to consider how treatment will affect their lifestyle — factors such as recovery time, lost wages and additional child care costs (94%). Women did agree however, that they should be more proactive by asking for alternatives (97%) and are quite likely to pursue a second opinion if they think they may be a candidate for a minimally invasive procedure that their own doctor does not offer (90%). Regarding the source for their information, 42 and 43 percent cited the Internet and their gynaecologist, respectively, as the first place they would go to learn more about their gynaecologic options. [1]

Do patients know about these techniques and if they could be applied to them? Less than 50% patients with menorrhagia knew about endometrial ablation; 45% of those with fibroids heard of myomectomy; 19% knew of ambulatory endoscopic sterilisation techniques. The authors cited different reasons for why the doctors did not offer this alternative and appropriate counselling to their patients:

- self referral (not being trained or confident in the advantages of these techniques)
- reimbursement- the health system did not differentiate (or even ignored ) the endoscopic surgery in regards to more “classical” surgery
- contraindications for endoscopic surgery procedures

What should the endoscopic surgeon “offer” to the patient soliciting these techniques?

In the article of Shenoy G 2009 [2], he mentioned that the law in most
developed countries ask “to care” not “to cure”; in other words, the surgeon’s role is not to assure the client of the result, but that he has the adequate training and acts according to general approved standards. Nevertheless, in medical specialties (internal medicine) the question is “what went wrong?”, while in surgical specialties is “who did wrong?” so many times.

In her article, Mettler 2013 [3] cite the following reasons for litigation, with other articles also in the same direction:

1. disappointing outcome, including lack of diagnostic after the procedure
2. intraoperative events 32%
3. failed/ incomplete diagnostic 17%
4. unrecognised complications 7% (especially entry related) [4]
5. failed sterilisation 6%
6. inadequate consent 5% -21% [5]
7. Other causes 3%

Therefore, as mentioned in Jena 2011 [6], there is a high risk of litigation even in gynaecologic surgery (close to 8% per year), even if other surgeries record higher numbers. In their conclusion, the authors considered that risk of malpractice claim during a career is, by the age of 65 years, 75% of physicians in low risk specialties (including gynaecologic endoscopy).

What would be the recommendations?

If >75% of us will meet with more than 1 litigation in our career, how to postpone and manage the inevitable?
1. Informed consent
2. Adequate (certified) training
3. Risk management strategies
4. Better inter - colleagues communication (inter and intra-specialties?)

1. The informed consent:

Informed consent is an integral part of any surgical procedure, and it should state the rationale behind the proposed surgery, the intended benefits, what alternatives could be provided, what are the risks and complications. Although there are differences between laparotomy and laparoscopy aspects, few services provide a separate consent for endoscopic surgery. In laparoscopic hysterectomies, 1 in 20 cases will experience a complication in supplement to abdominal hysterectomy [7]. Entry complications are specific, and not always related to experience - in a Dutch study 18% of malpractice claims were related to these accidents, but there were only in 6% claims from properly consented patients [4]. Another frequent event that some patients perceive as a failure, if not properly consented, is the conversion to laparotomy- in up to 25% of laparoscopic hysterectomies [8].

Unfortunately, there are no standardised methods used for the “best” informed consent. In a study of Ghulam et al [9], which evaluated the feedback from informed consent of patients going through gynaecological surgery, the authors mentioned that:

- the patients received oral and written (leaflet) information- and this lead to 80% satisfaction rate.
- More than half felt reassured by the exhaustive data received
- But 7% increased anxiety- especially related to language difficulty, or unclear written description of planned operation

Therefore, the authors also concluded that appropriate consent
should be obtained in the day of surgery if possible, but after a previous written information provided (leaflet, web sites recommended by doctors)

2. The adequate training
   
   This seems a logical approach, that no specialist should not interact with human patients until properly trained and certified.

   Nevertheless this is not done as it should be, and this is for several reasons:
   
   A) the training system is not standardised in curricula, duration and pre-requirements
   
   For example, AGES (Australasian Gynaecologic Endoscopy and surgery) [10] has the following criteria for trainees in endoscopic surgery:
   
   - Academic abilities (specialty, academic achievements)
   - Clinical expertise (clinical ability and judgment proven by their professional past)
   - Professional qualities (interpersonal and communication skills with patients of various backgrounds, families and staff)
   
   Different systems are proposed by the German Gynaecologic Endoscopic working Group, MIS I-III, or more recently by the European Society for Gynaecologic Endoscopy (ESGE) – the GESEA certification [11].

   The GESEA educational program provided by ESGE targets all gynaecologists practicing endoscopic surgery to have a common starting educational platform. Basic knowledge and principles of surgery in general surgery and specific in endoscopic techniques as well as hands-on abilities tested by psychomotor skills such as camera handling, hand-eye coordination and bi-manual instrument handling in the pelvic environment and stitching and knotting procedures. The GESEA programme ensures that board certification provides surgeons with recognizable skill levels and standard of excellence. Assessment and certification is considered to be the gold standard in assuring that a surgeon has acquired and retained a certain level of knowledge, skills and performance. GESEA programme allows the introduction of 3 brevetting levels. Level 1 is a Diploma of ESGE Bachelor in Endoscopy, Level 2 is a Diploma of ESGE Gynaecological Laparoscopist or ESGE Hysteroscopist or ESGE Gynaecological Endoscopist and Level 3 is a Diploma of ESGE Laparoscopic Pelvic Surgeon.

   B). The continuous training of gynaecologic endoscopist.

   The interest to improve knowledge and updating on techniques and new equipment and instruments is clearly the surgeon’s responsibility. Patient safety issues arise with the diffusion of a new procedure – based technology. The loss of tactile input is the major factor in making minimal access techniques difficult to learn. The threshold of 25 - 30 cases is mandatory before surgeons attain proficiency. This proficiency becomes greater as the complexity of the procedures grows, hence 90% of injuries are predicted to occur during the surgeons’ first 30 cases [12]. Surgeons who performed procedures without additional training were 3 times more likely to have at least one complication compared with surgeons attended additional training [13]. All above are serious considerations that can change the decisions by a court for or against a doctor in a complicated case. However, once a surgeon has been through training and testing and certification
his position in the court might have a favorable perspective.

C) Should the training be performed on patients, or on models?

The practice on human patients should be regarded with caution, although it still holds a majority in the endoscopic gynaecologist trainings.

Today is considered mandatory that a young gynaecologist interested to practice gynaecological endoscopy, laparoscopy and hysteroscopy should have excellent basic theoretical knowledge on the subject, should undergo training in simulators, dry and wet lab, training on animal models, certification and then initiate practice under supervision until experience gained.

In July 2014 an important recommendation on endoscopic training and quality assurance was signed and agreed by 6 professional societies in Europe and USA [14]:

ESGE (European Society for gynaecologic Endoscopy)  
EBCOG (European Board and College for Obstetrics and Gynecology)  
EAGS (European Academy for gynaecologic Endoscopic Surgery)  
ENTOG (European Network of Trainees in Obstetrics and Gynecology)  
ACOG (American College of Obstetrics and Gynecology)  
AAGL (American Association for gynaecologic Laparoscopy)

They strongly recommend that each hospital teaching endoscopic surgery should make available an endoscopic dry lab for training and improving the proficiency of the endoscopic surgery skills of the physician. Evidence is provided that dry lab training prior to training in the OR, reduces patients' morbidity and mortality in all endoscopic surgical disciplines, and as such the skill testing infrastructure should aim for multi-disciplinary usage [15]-[21]. Such statements will be used in the courts to indicate the professional level, responsibility, as well as the hospital management measures.

Figure 1. Joint statement of ESGE, EBCOG, EAGS, ENTOG, ACOG, AAGL [14]

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The risk management strategies

There are different protocols that deal with risk management in surgery, and they could be adapted to gynaecological endoscopy- for example, see Haynes et al 2009 in NEJM. But again this has to be a part of authority position, as it should be implemented both in daily life and in special situations (medico-legal situation especially) [22]

The great advantage of endoscopic surgery either hysteroscopy or laparoscopy to see better the operating field and to observe details that you cannot watch by laparotomy raises another ethical and legal issue in those cases that complications occurred after laparotomy. We must admit that, according to Chapron studies [23], there are no significant differences between the complications of gynaecological laparoscopic surgery and the laparotomy ones.

Continuous medical and surgery education should involve hot issues like new procedures and reassurance of how to manage complications. The risk of complications depends not only on the surgeon’s experience but dramatically on the surgeon’s knowledge and current practice. This emphasizes the need of learning the anatomy, strict follow up of surgery rules, learning the suturing techniques and other important procedures, learning the principles of energies, learning the new techniques and procedures.

Better inter- and intradisciplinary communication, to provide the patients with more accurate information.

This principle, valid in many fields of medicine, are even more important in endoscopic surgery for several reasons:
- specificity of complications
- the dependence on equipment technical development
- the unstructured training (short and long-term)

Some directions could be:
- Debate forums with experts and novices (moderated by experts)
- Free journal access (open access publications) or institutional support for that
- High level scientific meetings combining practical and theoretical aspects
- Feedback on protocols, complications etc.
- Available data on national and international situation regarding management of different procedure and complications.

Conclusions

Knowledge, skill acquisition, ethical matters as well as issues of principle will appear in the medico-legal cases once the number of certified surgeons will increase. In parallel national health systems and hospitals will demand and hire doctors with high and specific proficiency to endoscopic surgery. In Germany every endoscopist surgeon must perform at least 500 major operations in order to
be eligible to continue his surgery activities because under these circumstances patients’ safety is secured.

Last but not least, in the unwished event of a medico-legal case, the experts should be aware of the limitations that individual experience provides, that the most important are the aspects of safety and good information of our patients, and that, given the importance of the equipment, the gynaecological environment of the hospitals should be part of the legal solution.

References
[1]. Miller CE. You say you want a revolution... OBG Management 2010;22:7