

# The influence of carrying out multicentre trials on surgical practice in general surgery departments

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Videosurgery and other miniinvasive techniques 2009; 4 (1): 20–25

## Abstract

**Introduction:** Despite the introduction of treatment guidelines, hospital practice differs from the described standard. Data reported by the Polish National Fund of Health show that only about 50% of hernias are repaired using an implant. This study evaluates the influence of multicentre trials on daily practice in general surgery wards.

**Material and methods:** In the years 2002-2006, the Polish Hernia Study Group conducted 3 randomised trials involving the use of implants used in tension-free methods. Seventy-two doctors were questioned before the trial and at the end of the study. In the questionnaire, factors influencing the choice and the trust in the operating method, the sources and the accessibility of scientific information, the doctors' educational needs and factors able to influence the change of the operating technique were studied.

**Results:** Information from the literature was noted as the most important factor influencing the choice of operating method (64%). Also 70% of respondents based their decision on trust in the operating method. Trust in the results of research available in the literature grew considerably (from 65 to 95% of respondents), as did trust in the information delivered by the representatives of medical companies (from 8 to 39%). Level of confidence in older colleagues, that is in the trends dictated in respective centres by ward heads, fell from 78 to 21%.

**Conclusions:** Carrying out multicentre trials on surgical practice in general surgery departments increases the standard of treatment and motivates surgeons to research modern operative techniques.

**Key words:** inguinal hernia, treatment strategy, surgeon's choice, standards of treatment, surgical practice.

## Introduction

The introduction of tension-free methods in the second half of the twentieth century altered the surgical technique of inguinal hernia repair. A meta-analysis conducted in the years 1999-2002 by the EU Hernia Trialists Collaboration showed the superiority of techniques using synthetic implants over classically applied tension methods [1]. Percentages of recurrences, postoperative pain and the time of convalescence were considerably reduced. The results of published research became the basis to

work out standards for the treatment of inguinal hernia in the countries of the European Union, and also in Poland, which show the necessity to use tension-free methods (or alternatively low-tension) in all primary cases of inguinal hernioplasty in adults [2-5]. However, in spite of introducing such directives and propagating them in the forums of national surgical and hernia societies, hospital practice differs from the described standard. In Poland, in spite of the introduction in 2003 of standards of hernia treatment, data reported by the National Fund of Health show that only about 50% of hernias are

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repaired using a synthetic implant [6]. Similarly, in western countries (England, Scotland, Denmark) and in Japan the percentage of hernioplasty without implant is 18-20% [7-10]. This problem is a focus of discussion in the forum of the European and American Hernia Societies. Its essence is to convince operating surgeons, usually not focusing their interests on hernia repairs, to apply new operating methods, and, consequently, to change the practice in the departments of general surgery. The topic of this paper is the influence of carrying out multicentre trials using the Lichtenstein technique on operating surgeons' attitude and trends in surgical centres.

## Material and methods

In the years 2002-2006 the Polish Hernia Study Group conducted three randomised trials involving the use of new synthetic implants used in non-tension methods. The trial relating to the mesh Ultrapro® (Ethicon GmbH, Hamburg, Germany) was conducted in 15 hospitals, that relating to the mesh WN (Surgimesh WN®, Aspide Medical, France) in 5 hospitals, and that relating to the absorbable implant (APG®, Gore & Asc.) in 2 hospitals. The hospitals were divided into large academic hospitals (3 hospitals) and remaining field hospitals. The doctors' attitudes were assessed before the beginning of the trial and at the end of the period of including patients in the trials (2-3 years later). Seventy two doctors were questioned, including 49 surgeons and 23 anaesthetists. In the questionnaire, factors influencing the choice and trust in the operating method, sources and accessibility of scientific information, the doctors' educational needs and factors able to influence the change of the operating technique were studied. During the trials meetings for the researchers were organised. Their aim, apart from discussing the research, was to improve the operating technique, discuss the scientific literature and present new medical materials. Critical panel discussions concerning the value of the scientific research and the way of their interpretation (the EBM) were carried out. Additionally, in the final questionnaire conducted after a period of one-year observation of the patients (2005) it was checked what influence in the doctors' opinion participation in the trial had on the introduction of operating standards, anaesthesia and conducting long-term observations, and also gene-

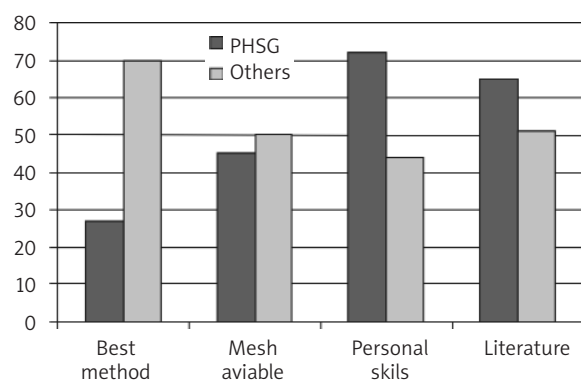
rally on the improvement of the quality of inguinal hernia repair. The construction of the questionnaire was identical to the one carried out in 2002 to check the attitudes of surgeons from the Pomeranian Province, which enabled us to compare both the output results, and to follow the trends of change during the trial [11]. The results presented in the previous publication come from the questionnaires carried out in 19 hospitals of the Pomeranian Province, where 119 general surgeons were questioned.

In the calculation, the per cent participation of chosen answers or the average for categorical data were taken into account. Results are presented in two time points.

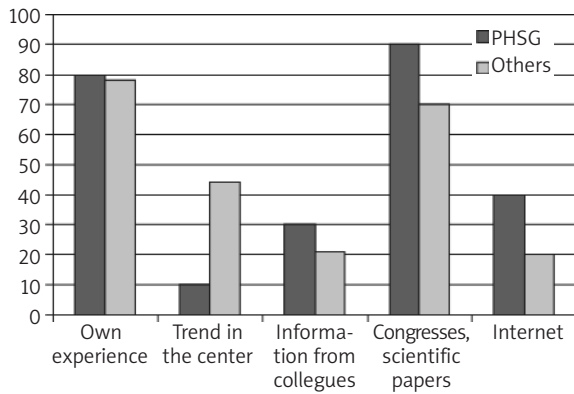
## Results

In estimating the factors influencing the choice of operating method it was noted that the most essential was information from the literature (64% questioned) and personal skills of the operating surgeon – familiarity with the operating technique (70%). The trust in the operating method had a smaller significance (26% questioned), as had the accessibility of synthetic implant (43%). Comparing these data with the ones previously gained among surgeons of the Pomeranian Province, it was observed that proportions arrange inversely. The majority (70%) base their decision on trust in the operating method, and remaining parameters are less important (Figure 1).

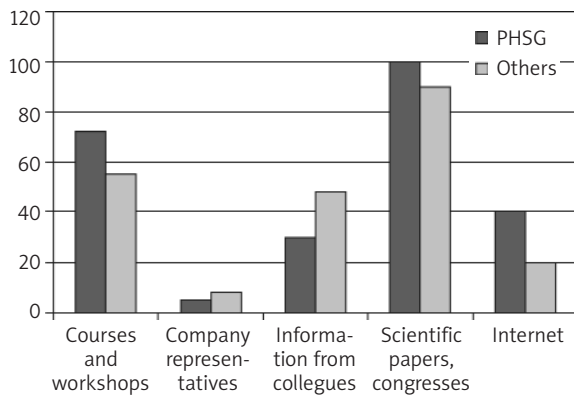
When estimating the factors having an influence on trust in the method, scientific information gained



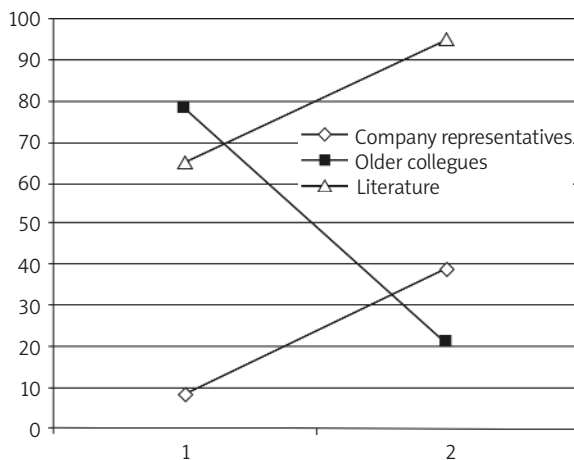
**Figure 1.** Factors influencing the choice of operating method in the researchers' group (others – comparison with surgeons of Pomeranian Province)



**Figure 2.** Factors influencing trust in the method (others – comparison with surgeons of Pomeranian Province)



**Figure 3.** Sources of credible information that might have an influence on change of operating technique method (others – comparison with surgeons of Pomeranian Province)



**Figure 4.** Trust in factors having an influence on change of operating technique before (1) and after (2) the trial

during conferences and scientific symposia (90% of respondents) or from the Internet (40%) played an important role. The influence of routine practice in a given centre had an insignificant influence on researchers' attitude (10%), which differentiates the questioned group from the surgeons of the comparative group, in which this factor was considerably higher (40%). The influence of respective factors is illustrated by Figure 2.

When estimating the factors having an influence on the change of the operating method, respondents specified potential sources of trustworthy information which could bring such a change. Questioned researchers from the PHSG group treat information gained during scientific congresses, courses and workshops with the greatest confidence and information passed on by their colleagues plays a lesser role. Information passed on by the representatives of pharmaceutical corporations is treated as credible only by 8% of researchers and 9% of surgeons in the comparative group (Figure 3).

In the supervisory questionnaire conducted in 2005 estimating the influence of trials on the opinion of surgeons engaged in PHSG works, 3 main changes relating to the factors influencing the choice of the operating method were stated. Trust in the results of research available in the literature grew considerably (from 65 to 95% of respondents), as did trust in the information delivered by the representatives of medical firms (from 8 to 39%). Inversely to these two factors, the level of confidence in older colleagues, that is in the trends dictated in respective centres by ward heads, fell from 78% of declaring respondents to 21% (Figure 4).

In the additional questionnaire illustrating the influence of the research on everyday practice of given surgical wards it was found that the operating technique applied in the research became a routine operating technique in 75% of hospitals taking part in the trial. Similarly, the standardisation of anaesthetic technique was introduced as routine in 40% of hospitals. Every fourth hospital, as routine for all patients operated on for inguinal hernia, also introduced description standard and follow-up. Eighty seven percentage of those questioned stated that the conducted research contributed to the improvement of the quality of hernia treatment in their centre. Those questioned also stated that taking part in the research encouraged them to research new techniques and operating materials (84% of res-

pondents), and review the literature of hernia treatment (100%). Similarly, 100% of respondents declared their willingness to take part in the next research. In free motions about the research it was also noted that young doctors learnt the classification of hernia and the operating methods, the majority of older doctors were convinced to use tension-free methods, the attitude of doctors from the field hospitals towards clinical research became positive, and interest in the problem of hernia was growing.

## Discussion

The improvement in the quality of offered medical services is based on doctors' knowledge, the evaluation of their own practice, and their ability to change their individual standards of treatment. Therefore it is fundamentally connected with monitoring their own practice and presenting the results in order to identify the behaviour requiring improvement [12]. There are several possibilities to influence the change of doctors' behaviour in the treatment process. The most essential are the delivery of scientific data based on the facts (EBM), standards based on EBM, possibilities of professional postgraduate education, tests checking knowledge and medical practice, and assessment of the general quality of treatment [12]. Unfortunately, all these factors are subject to limitations because of the individual doctors' behaviour, but also the incoherence in the opinion of scientific societies. Cabana *et al.* analysing the problem of translating the treatment standards into clinical practice specified several factors holding back this process. The essential objective factor is the quantity of new clinical research appearing in the scientific literature and the specific scientific language. This leads to the conviction of doctors that it is impossible to comprehend all accessible knowledge, and this restricts the possibility of development. Similarly, practitioners' opinion has an influence on not respecting guidelines based on EBM. Doctors do not believe that these guidelines have an essential influence on the result of treatment; sometimes they do not see the possibility of introduction of standards because of their surroundings. Mainly, however, they lack motivation to change what stems from their high evaluation of their practices, habits and routine so far [13]. Similar conclusions can also be drawn from data presented in this work. Comparing the participants of PHSG

research to the general population of surgeons, we found out that their willingness to take part in the research (notification of willingness to work in the research) is not accidental but results from their higher motivation to search for new solutions in the treatment process. However, not only motivation has an influence on improvement of the quality of treatment, which was observed in the questionnaire research carried out after the PHSG trial. Analysing the influence of different factors, Davis and colleagues found a large influence of practical trainings on the quality of the medical services offered in a given hospital. In contrast to lectures given by experts, which do not have an influence on doctors' everyday practice, constant training in small groups combined with improvement of practical skills makes this practice significantly better [14]. Similarly, Berholz, describing the practice of the Johns Hopkins Hospital in Baltimore (MD, USA), points to the significant role of continuous training and monitoring the phenomena in the process of treatment by an independent team. This leads also to improvement of collective work; it opens the field for discussion and consolidates team work [12]. Team work and discussions also have an influence on the acceptance of guidelines worked out by experts. In the places where the intervention is more individual, acceptance of guidelines falls. Doctors perceive standards as "a cookbook" limiting their autonomy, impractical and inflexible [13]. Gatellari in his work studied the influence of opinion leaders on practice and propagating standards [15]. The opinion leader as a person endowed in the doctors' environment with authority has a great influence on the improvement of the quality of treatment, but only this in connection with different activities such as audits, monitoring results of treatment and ongoing education leads to significant progress [15]. The results of treatment of hernia in Poland show that also in recent years the percentage of use of synthetic implants in inguinal hernia repair imperceptibly exceeds 50% [6]. In the face of the above described dependences it should be noted that such a situation is the derivative of everyday practice of hospitals. Neither the National Fund of Health nor the hospitals keep registers permitting a thorough evaluation of results of treatment. A patient's observation ends at the moment of discharge from hospital and a patient suffering because of complications is often seen by a different doctor. Such practice considerably limits

the possibility of critical evaluation of a doctor's own accomplishments and the decision about the necessity to introduce some changes. In the presented material surgeons univocally estimated that carrying out observation in clinical research for many months has a positive influence on everyday practice. Even the necessity to record the results for the research made the operating surgeons observe the standards and raised the quality of services. It should be underlined that this phenomenon did not concern only surgeons participating in the research directly but whole medical teams, also more than once including anaesthetists. Similarly, trainings and discussion panels carried out during the research caused the growth of interest in scientific publications and the development of operating methods. The fall of confidence in the ward head's opinion coexists with this phenomenon, which allows a departure from routine and a search for clinical solutions on a wider field. It is interesting that the opinion about medical corporations was considerably changed. Before the research they were perceived as exclusively trading companies gaining market share. During the research nearly half of the surgeons appreciated the fact that medical corporations organised constant trainings and promoted scientific studies based on EBM.

In many aspects the participants of research noticed some positive changes in the activity of whole medical teams, in spite of the undertaken effort connected with filling the records and carrying out follow-up. A hundred percentage of participants declared a willingness to take part in the research again. In the authors' opinion carrying out a randomised clinical study in field hospitals has an influence on clinical practice. A study designed in such a way fulfils all the criteria of putting the results of scientific research into practice. It delivers experts' opinions and literature, and it allows trainings of surgical practice to be carried out. Such practice, by including the patients in the research, becomes a daily routine of the ward and the results of its introduction are monitored by supervisory visits allowing for verification.

## Conclusions

Summing up, carrying out the prospective research at hospitals can have a considerable influence on improvement of results of the treatment of a given illness. Such conclusions require considering the introduction of voluntary registers

permitting epidemiological phenomena to be monitored in herniology as it is practised in neoplastic diseases.

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## Appendix:

The Polish Hernia Study Group consists of:

- project leader: Śmietański M (Gdańsk),
- steering committee: Bigda J (Gdańsk), Łukasiewicz J (Gdańsk), Łukiański M (Gdańsk), Witkowski P (New York, USA),

- scientific advisory board: Matyja A (Kraków), Śledziński Z (Gdańsk), Śmietańska IA (consultant anaesthesiology, Gdańsk), Owczuk R (consultant statistician, Gdańsk),
- trialists: Bierca J (Warszawa), Bury K (Gdańsk), Dideńko W (Warszawa), Gąsiorowski A (Zgorzelec), Gebuza A (Wrocław), Gumela P (Gdańsk), Jędrasiak D (Warszawa), Kamiński Z (Biała Podlaska), Kątny T (Bydgoszcz), Kniaź M (Wrocław), Kostewicz W (Warszawa), Kurzyński M (Zgorzelec), Kwiatkowski A (Warszawa), Leszczyszyn J (Wrocław), Łebski I (Wrocław), Malińska K (Środa Wlkp.), Mazur A (Kędzierzyn-Koźle), Olejarz A (Bydgoszcz), Orłowski P (Warszawa), Paradowski T (Bydgoszcz), Paśko K (Wrocław), Perczyński W (Warszawa), Piotrowski R (Koszalin), Ryll P (Środa Wlkp.), Sachanbinski T (Opole), Sawicki M (Warszawa), Skoczylas M (Wrocław), Solecki R (Kraków), Szczepanowski A (Kędzierzyn-Koźle), Timler D (Łódź), Trojanowski P (Warszawa), Wiśniewski W (Warszawa).