Sustaining Mature Womens Health: Outcomes after pelvic organ prolapse surgery. Development and use of a previously unprecedented national 5-year follow up questionnaire

Background:

Pelvic organ prolapse (POP) is a prolapse, or "drooping", of the pelvic organs (such as the bladder, uterus or rectum) into a womans vaginal canal. This condition has a negative impact on everyday functions and can cause considerable pain. [1]

Up to one fifth of all women will have an operation for POP during their lifetime. [1-3]

In Addition, among the 4000 patients operated in Sweden each year, more than one-in-four will have recurring symptoms 1 year after the surgery. [4-6]

Despite this both a high prevalence and recurrence rate, there is virtually no information of the long term results of this condition. No studies have been published who systematically scrutinize the long-term results of the operations, and the complications that may arise. Theories on the long-term results are based on few, minor studies with a 1-2 year follow up, combined with case studies. Age, time of estrogen deficiency and weight are supposed to deteriorate the results over time.
The longest follow up period published using a large material is only up to 1 year postoperatively. [1,2,4,6-8]

This leaves surgeons speculating which operative method is best in the long run, or if it is indeed beneficial to operate at all.

Conducting a considerably longer follow up than one year, however, has been impossible to carry out anywhere else in the world.

It would require a *substantially validated database*, able to identify individual patients. In addition, implementing *tested and validated questionnaires*, with detailed preoperative health data as well as detailed operation- and postoperative data.

The Swedish national register for Gynecological Surgery (GynOp) fulfils all of these criteria.

The GynOp Database:

According to Läkemedelsvärket in Sweden and the European SCENHIR (The Scientific Committee on Emerging and Newly Identified Health Risks), no systematic registration of all available operative methods on a national level exists in any of the EU countries, with the exception of Sweden and the Netherlands(who have recently started registering POP data).

Since 2006, GynOp all major gynaecological surgery including incontinence, prolapse and tumour operations. Coverage comparison made to the national central database of healthcare (The Swedish national inpatient register), where all patients must be registered according to Swedish law, shows, that 95 % of the patients in the inpatient register are found in GynOp and vice versa.

The Questionnaires:

Patient questionnaires were designed, constructed, and validated by the Department of Educational Measurement, Umeå University, Sweden.
In daily routine quality control of surgery, GynOp implements questionnaires 3 times: preoperatively (QP), two months postoperatively (Q2), and one year postoperatively (Q12). These are answered by the patients and returned to the gynaecologist for evaluation, and answers are pooled into a central database.

In the QP, patients report symptoms, general health, preexisting conditions and lifestyle-factors. Short medical follow-up questions are answered in the Q2.

The Q12 include questions identical to those on the QP, as well as questions about long-term complications. [9-17]

The overall response rate is around 90%. The questionnaires are sent electronically to patients with registered email addresses, and remaining patients receive paper-questionnaires. Roughly 60 % of the patients answer directly on the Webb. First and second reminders are sent when applicable.
The surgeon's forms include preoperative data concerning physical and gynaecological examinations of the patient. Detailed information about the operation and postoperative events are noted, including histopathology findings when present. Previous studies show high validity in the register data. [9-17]

Due to a national cooperation, a 5-year-questionnaire that can be used to follow-up patients after POP has already been developed, validated and ethically approved within GynOp.

Therefore, a novel study of the 5-year outcomes on after POP surgery on a national scale is possible.

However, the funding of a specific research project is outside the obligations and possibilities of the register, and thus dependent on external funding to conduct this essential study in omen's health.

Aim:
To achieve an overview of the long-term results (up to 5 years) of POP surgery.
To assess to what extent the operative methods are beneficial for women in a long-term perspective.

Methods:

The overall intention is to send a questionnaire 5 years after the operation, to all patients who have had surgery for pelvic organ prolapse. The permit from the clinics for contacting these patients is already obtained.

Within GynOp, patients are registered with the exact surgical method used during their operation. For example, those who have received implants (the newest surgical method) are registered as such, and can be completely identified and targeted when sending out questionnaires. In addition, identifying and contacting a subset of patients who do not have a surgical implant, that can be used as a comparison, is also possible.

The survey includes questions used in the follow-up questionnaire 1 year after surgery, as well as in the health declaration preoperatively. Questions also regard issues relating to symptoms associated with prolapse, public health issues, as well as symptoms and any measures taken at the sign of recurrence of prolapse. Patients also report complications related to the completed surgery, that have occurred since answering the previous questionnaire.

Some new questions have been designed for patients operated with a surgical implant, since the implant-specific issues are missing in the 1-year questionnaire.

The survey begins with informing the patient about the research study, and that participation is voluntary. The women are informed, that data is processed in a de-identified form and that responses cannot be traced back to a single person. The questionnaire and the information letter was tested and validated, first as a face-on validation (using 30 Swedish-speaking medical students), and further in pilot-studies three times, each consisting of 20 patients (prolapse with and without implants) operated five years ago. The regional Ethics-committee in Umeå, Sweden, approved the study. Reg. No. 2015-288-31 m

The survey responses will not go to the attending clinic for assessment, but directly to the research team for analysis. Assessment of possible serious complications, however, will be communicated to the clinics for survey and possibly treatment. The inquiry will primarily only be sent in electronic form to patients registered in ”1177”, or alternatively to the patients who have an email address known to the register, as well as in paper form to the patients who do not have an e-mail address and who have received implants inserted. This is done to increase coverage for implants.

In 2012, 4558 POP operations have been registered, and of those, 490 had implants.

Power calculations have been made with regards to the study questions. The data collection regarding Implants must reach > 500 cases, to be able to make risk assessment of implant erosion down to the 1% level. Intermediate analyses will be made for the assessment of major risk factors linked to implants.

A pilot test indicates a response rate of about 60%, which seems reasonable to expect in the actual study.

Therefore, the study is expected to need two years of material to achieve around 500 patients operated with implants and 1600 operated without implants.

Because the input values regarding risk factors for prolapse are available for the entire population, the results take into account the expected imbalance in educational levels (and thereby lower parity) in the population, notified through “1177” or via E-mail. [17]

Research question

Are the operative methods in POP-surgery, beneficial for women in a long-term perspective?
What is the influence of age and weight on recurrence frequency
Which women benefit, from which surgical procedure, under what circumstances?

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