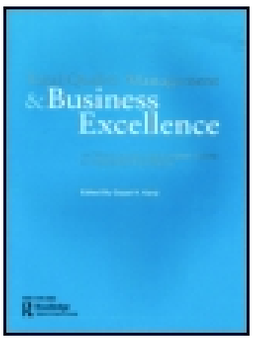

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The influence of geographical and clinical factors on decisions to use surgical mesh in operations for pelvic organ prolapse

Emil K. Nüssler[a]*, Emil Nüssler[a], Jacob Kjær Eskildsen[b], Dorthe D. Håkonsson[b,c], Mats Löfgren[a] and Panagiotis Mitkidis[b,d]

[a]*Department of Clinical Science, Obstetrics and Gynecology, Umeå University, Umeå, Sweden;* [b]*Department of Management, School of Business and Social Sciences, Aarhus University, Aarhus, Denmark;* [c]*Department of Business Development and Technology, School of Business and Social Sciences, Aarhus University, Herning, Denmark;* [d]*Center for Advanced Hindsight, Social Science Research Institute, Duke University, Durham, NC, USA*

Background: Surgical mesh can reinforce damaged biological structures in operations for genital organ prolapse. The first mesh products were cleared by the U.S. Food and Drug Administration in 2002. In contrast to stringent requirements for the development of pharmaceuticals, there was never a systematic scientific evaluation of mesh products. ***Purpose***: We examined whether Swedish gynecological surgeons have transformed increasing amounts of scientific information into common learning, resulting in a convergent and consistent pattern of mesh use. ***Methods***: Based on data from the Swedish National Quality Register of Gynecological Surgery, registered from 2010 to 2016, we examined changes in decisions to use mesh in a largely uniform group of 2864 recurrence patients operated by 455 surgeons, where surgical mesh was used in 1435 patients (50.1%). By means of logistic regression, we explained decisions to use mesh by clinical risk factors, an FDA warning, year of surgery, type of hospital, and geographical factors. ***Results***: The use of mesh in Sweden varied extensively, by a range from 7% to 93% on county level. These disparities were maintained between the entities over time. Different groups of decision makers had drawn different conclusions from the available information. Geography was the most important parameter in explaining decisions to use mesh. ***Conclusion***: Mounting scientific information has had no measurable impact on decision-making, and has not led to a more consistent decision pattern. Early decisions have led to obvious 'communities of practice' at county and region levels. Swedish surgeons, unaltered through 7 years, have made mesh decisions in a clearly biased fashion, highly influenced by geographical factors, and with no measurable change towards national consensus.

Keywords: health care; decision-making; quality assurance

Introduction

Pelvic Organ Prolapse (POP) is common in women. 30–50% of women over 50 years of age have some degree of POP. The lifetime risk of undergoing an operation for POP is approximately 12% (Fialkow, Newton, Lentz, & Weiss, 2008) and high rates of recurrence in the range of 30–40% (Maher, Feiner, Baessler, & Schmid, 2013) have been reported.

Surgical mesh is intended to provide additional support to weakened or damaged biological tissue, and specifically designed meshes have been used since the US Food and

*Corresponding author. Email: emil.nussler@umu.se

Drug Administration (FDA) approved the first mesh products in 2002 (American Food and Drug Administration, 2002).

In the last decade, research on the use of mesh in POP has increased enormously. A PubMed search for '(Pelvic organ prolapse AND (mesh OR implant))' in August 2017 produced more than 2000 articles on the subject. However, treatment of POP with mesh remains controversial: The use of mesh in prolapse surgery may lower the risk of recurrence of symptoms, but also includes a potential risk of mesh-related complications (Maher et al., 2016).

In contrast to the stringent requirements and formalised approaches for development of pharmaceuticals, there was never a systematic scientific evaluation of mesh products. Faced with this situation, every surgeon individually has to investigate and validate available scientific information and accept the information gleaned as 'current best knowledge.' In such situations, a surgeon's assumptions or beliefs is likely to affect how the information is utilised.

The implementation of surgical innovations and new methods is the motor of progress in surgery. Yet, as long as a method is new, scientific information is often contradictory, and individual surgeons may accept different observations as useful, resulting in conflicting treatment strategies.

Decision makers are known to update their beliefs as they gain more information (Bayes, 1763). This information is reflected in their subsequent decision-making so that, when new information favours one alternative over another, this alternative will be chosen (Camerer, 1998; Hogarth & Einhorn, 1992). Based on this principle, the greater the amount of valid scientific information physicians receive, the more structured their beliefs should become, and the more convergence it is reasonable to expect in their decision-making patterns. Over time, learning-based information enables progress in two distinctly different directions: (1) enhancing the quality of the treatment process by developing optimal surgical techniques and devices, and (2) enabling learning regarding which patients can benefit from the new method, and under which circumstances.

Making good judgments that are scientifically informed and evidence based seems straightforward, but many times, despite the large experience and the extensive knowledge decision-making has a large space for errors and misjudgment. Research has shown that both emotional and cognitive limitations in information processing (Elstein & Schwartz, 2002) limit rationality. Biases affect the ways that people estimate and interpret evidence (Bornstein & Emler, 2001; Dolan, 1999; Elstein, 1999; Hammond, 1996; Hershberger, Part, Markert, Cohen, & Finger, 1994) such that identity and environmental factors have been shown to influence decision-making (Dawson & Arkes, 1987; Graber, Gordon, & Franklin, 2002).

For example, research on cognitive simplification processes has demonstrated how people tend to accept information that confirms their own hypothesis, and undervalue disconfirming information (Levine, 1971). Such biases may lead to a variety of clinical, geographical, and organisational factors having influence on the pattern of mesh usage insofar as 'communities of practice' are likely to form in which commonly held views on whether or not to use mesh are likely to influence surgical decisions. Biases are even more likely to prevail given the vast amounts of scattered information available to surgical decision makers (Black & Welch, 1993; Bornstein & Emler, 2001; Haynes & Haines, 1998).

Therefore, when introducing novel procedures, a regulatory framework is desirable to monitor the results and protect patients from potential harm. If evaluation is not done early in the process, there seems to be a tipping point, after which widespread adoption of the procedures may happen without adequate evidence (McCulloch et al., 2009).

So far, the focus of research concerning mesh has been on the evolution of the technical side of the method. In the last decade, there has been significant improvement in the quality of the surgical procedure. Development of better meshes and atraumatic treatment processes has matured the surgical technique. Even so, no surgical or medical remedy is ever so perfect that it is good for all patients in all circumstances. Consequently, decisions to use mesh cannot be based solely on the question of proof of superiority or inferiority of mesh in general. The crucial challenge for surgeons is to decide for which proportion of patients a native tissue repair will have a high risk of failure, and the documented benefits of a mesh repair outweigh the risks (Davila, Baessler, Cosson, & Cardozo, 2012).

A recent paper reporting on 684,250 POP procedures that were performed in 15 OECD countries in 2012 showed that the use of transvaginal mesh grafts in the anterior compartment differed by factor 7.9 (range 3.3–26%) and in the posterior compartment by factor 5.3 (range 3.3–17.0%) (Haya et al., 2015).

The optimal rate of mesh use cannot be both low and high at the same time. The extraordinary disparity in mesh use is unsettling and the large variation in surgeons' choices are bound to impact negatively on clinical care. Therefore, identifying the factors influential to such decision patterns is important.

The aim of this paper is (1) to describe, over 7 years, the disparity in the use of surgical mesh in operations for POP in Sweden and (2) to examine the effect of clinical risk factors, and organisational as well as geographical factors on Swedish gynecological surgeons' decisions to use mesh, and investigate whether the potential influence of those factors changes over time.

Methods

The Swedish national quality register of gynecological surgery (GynOp)

GynOp includes all gynecological operations performed in Sweden. Since 2006, GynOp has registered prolapse operations on a national scale, including a 1-year follow-up of patients. Today, the register contains complete information on more than 50,000 prolapse procedures, and the database is increasing by approximately 6000 new POP operations a year.All patients are included in the register when an urogynecological operation is decided. A comparison with the Swedish National Patient Register (where all Swedish surgical procedures are registered by law) shows that the GynOp coverage of Swedish prolapse operations since 2009 has continuously been >95%. The data collection process includes both surgeon and patient-derived data up to 1 year post-operation. The gynecologist completes a form about preoperative objective findings, an operation form describing the operation in detail, and a postoperative form at discharge. Data completeness regarding the use of mesh reported by the surgeons has been 100%.

The Swedish hospital system

The Swedish hospital system is first and foremost organised on county level. Sweden has 21 counties; an average county has around 400,000 inhabitants and 3 public hospitals. The Swedish counties are quite independent, self-financing organisational units responsible for all health service within their boundaries. Public service hospitals are owned by the counties and are for the most part financed via county taxes. Counties are grouped into six health care regions designed to provide tertiary level care, to facilitate cooperation, and to maintain a high level of advanced medical care. There are few private clinics that specialise primarily in elective surgery. Those clinics are contracted and reimbursed by

county councils for operations they perform on Swedish patients. All Swedes are covered under the national health system.

Practically all (98.2%) patients that undergo a prolapse operation are operated within the county they live in. In an effort to make the hospital system more efficient, some counties have gathered more specialised functions in certain hospitals, so differences in use of mesh on hospital level may in some clinics have organisational rather than medical reasons.

Therefore, we calculate the proportion of POP operations augmented by mesh county – and region wise, stratified by years, to express the particular mesh policy for a particular year. The resulting matrix makes it possible, from year to year, to analyse the impact of decision-influencing factors and changes in mesh use on county and regional level, as well as changes in distribution of mesh use on a national level.

Data

The basic data used in this study includes all POP operations registered prospectively and consecutively in GynOp from January 1st, 2010, to December 31st, 2016, in all 40,394 operations reported from 63 different gynecological departments. Patients with simultaneous operations for incontinence have not been included.

To minimise confounding, we included only patients which are (1) solely operated in the anterior compartment (anterior colporrhaphy) or (2) solely operated in the posterior compartment (posterior colporrhaphy). Those are common and comparable routine operations in prolapse surgery, of moderate level of difficulty, and are performed both with and without mesh. Patients with concomitant POP or non-POP operations were excluded. Additionally, (3) only healthy patients were included in the study [American Society of Anesthesiologists (ASA) preoperative physical status classification system group one or two]. Moreover, (4) all selected patients have a normal, not descended uterus. To avoid bias from very small, low active, or subspecialized clinics, we excluded 74 patients from 12 departments that had fewer than 100 POP operations or less than 20 recurrence POP operations through the observation period. Since it can be argued that primary and recurrent POP operations represent different, non-comparable patient groups, we analysed only patients undergoing their first recurrence operation, where the use of mesh is a generally accepted option. Mesh use in this group in Sweden has been stable around 50% in the whole observation period.

Our selection process resulted in a study group of 2864 eligible, largely uniform and comparable patients with recurrence POP surgery in the anterior or posterior compartment, operated by 455 Swedish surgeons, where surgical mesh was used in 1435 patients (50.1%).

Results

Basic descriptive statistics reveal that the use of mesh in our material varies substantially across Sweden (Figure 1). On a national level, the total use of mesh in the years 2010–2012 was around 57%. From 2013 (two years after the FDA warning), there was a significant decline to a new stable level around 43% (Figure 1). On county (and even regional) level, there was an unchanged, significant difference in mesh use, through the whole observation period of 7 years, independent of the 27% decline of mesh use on national level in 2013 (Figures 2 and 3). The difference between counties stands out: the lowest has a use of 7%, the highest of 93.2% (factor 13.3). Over time, counties continued to use mesh in roughly the same manner, maintaining the disparities between the entities (Figure 4).

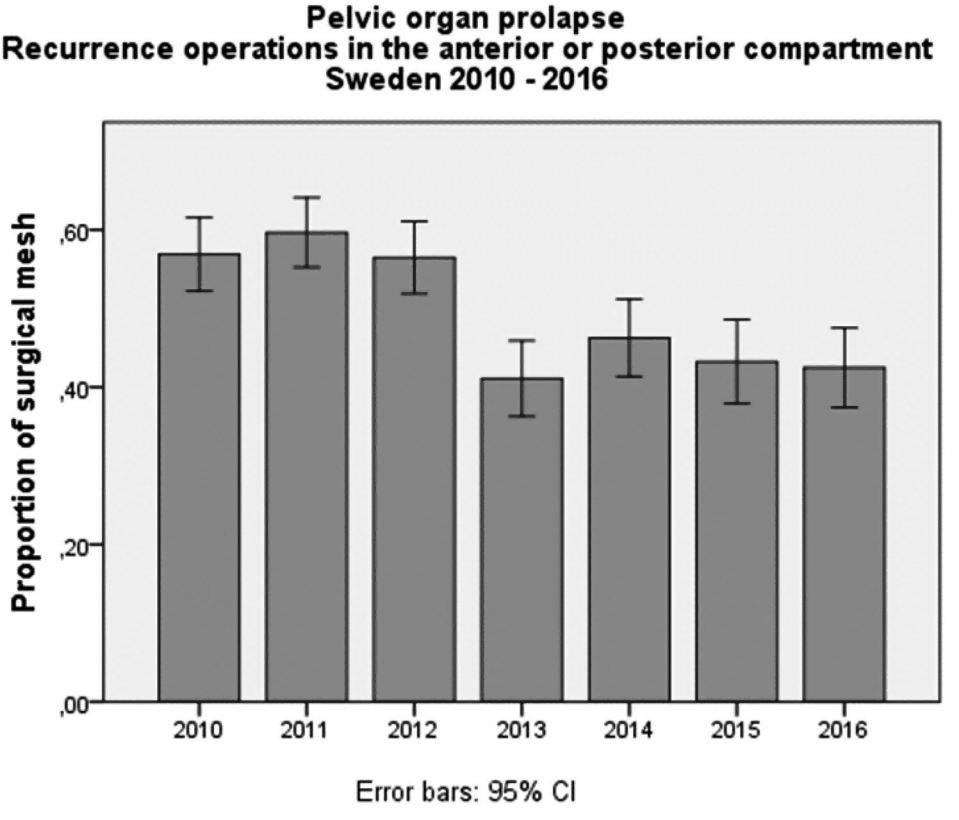

Figure 1. Use of mesh in Sweden 2010–2016 in operations for recurrent POP in the anterior or posterior compartment.

To gain a deeper understanding of these differences, the data was analysed in several steps using logistic regression. Statistical Package of Social Sciences (SPSS), version 20, was used for statistical analyses (SPSS Inc., Chicago, IL, U.S.). Initially, we attempted to explain the use of mesh using clinical parameters known to have an association with the development of POP (Vergeldt, Weemhoff, IntHout, & Kluivers, 2015).

The following parameters were included in this stage: Age, place of the POP (front/back compartment split), body mass index (BMI), number of vaginal deliveries, degree of prolapse (position of leading edge of prolapse in relation to the hymen), and sexually active (intercourse within three months before operation). Table 1 displays the results. As appears, degree of prolapse, age, and compartment split were the only influential parameters, whereas sexual activity, BMI, and number of vaginal deliveries were not influential.

Table 2 shows the model after all the insignificant parameters have been removed. As appears, the likelihood of mesh use increases with the degree of the prolapse and decreases slightly with the age of the patient. Furthermore, mesh is used more on front compartment prolapses.

The next parameter entered into the analysis is the year of surgery. This is done, because FDA in 2011 released an update and warning regarding the use of transvaginal surgical mesh: 'The FDA has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse (POP) based on a

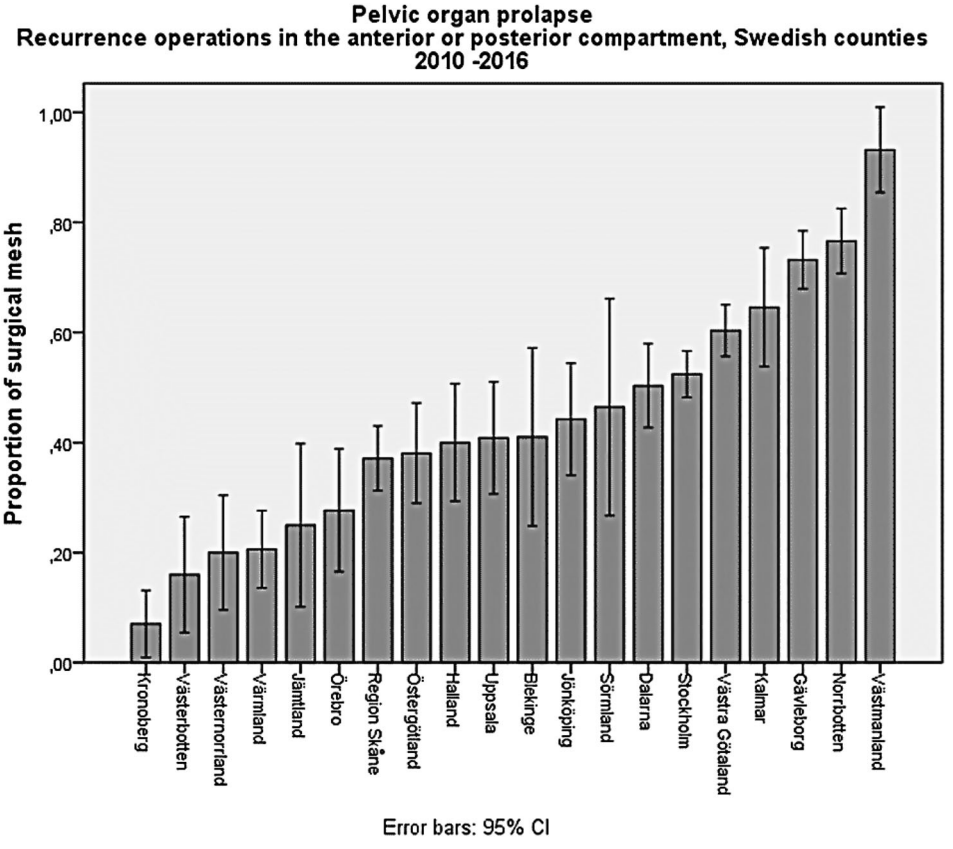

Figure 2. Use of mesh in Swedish counties 2010–2016 in operations for recurrent POP in the anterior or posterior compartment.

review of adverse events reported to the FDA and an assessment of the scientific literature.' (American Food and Drug Administration, 2002) We, therefore, wanted to see if the FDA warning had an impact on the decision to use surgical mesh in Sweden. As Table 3 shows, the effect of the FDA warning occurs later than expected. From 2013 and onwards, the frequency of mesh use is lower than in previous years. Interestingly, the differences between the counties/regions were not affected by the FDA warning.

Next to be included in the analysis is the level of care. We aimed to clarify whether mesh still is regarded as experimental procedure and done foremost as projects at university level.

In Table 4, the result stemming from this analysis is shown. As appears, the likelihood of mesh use is higher at regional hospitals.

Since neither medical factors nor regulatory warnings were influential to decisions patterns, but level of care was, consistent with the theory on biases, we wanted to examine whether geographical factors were influential. We, therefore, included region and county into the analyses. As Tables 5 and 6 show, geography is by far the most important parameter when it comes to explaining the use of mesh in Sweden (see also Figure 4). The explanatory power of the model can be raised to 0.457 by including the individual hospitals in the analysis (Figure 5).

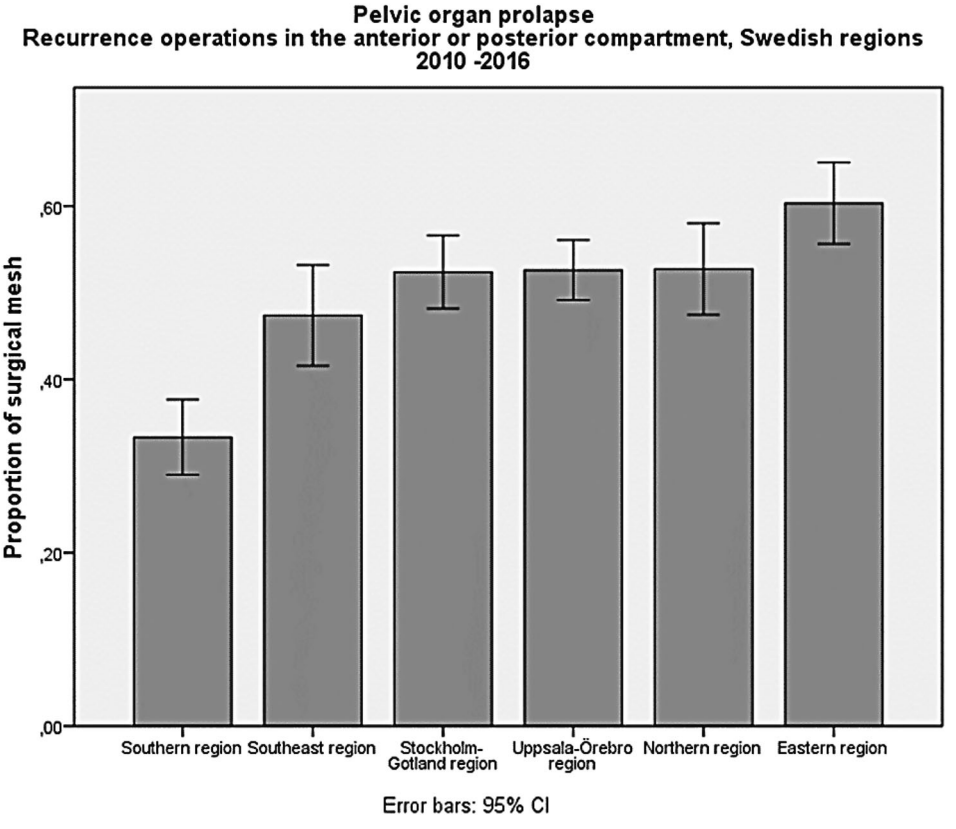

Figure 3. Use of mesh in Swedish health care regions 2010–2016 in operations for recurrent POP in the anterior or posterior compartment.

Discussion

To monitor mesh use on a national scale, we have followed 455 Swedish surgeons over 7 years conducting 2864 POP operations on comparable patients with recurrence POP surgery in the anterior or posterior compartment. We have analysed the distribution and rate of mesh use in Swedish counties and regions, stratified by years.

We found that the use of mesh varies extensively across Sweden (between counties by factor 13 and on a regional level by factor 1.8). There has been no measurable change towards consensus on county or regional level through 7 years. An FDA warning in 2011 leads to a lowering of mesh use around 14% from 2013 an onwards, two years later than expected. The disparities within the counties/regions were not affected by the FDA warning. Mesh use increases with the size of the prolapse and decreases slightly with the age of the patient. The likelihood of mesh use is higher at regional hospitals than at university hospitals, showing that mesh is widely used as a routine procedure in the whole country.

Mesh is administered more often in the front compartment than in the back compartment, in all departments, counties, and regions, unchanged over time. We interpret this difference as the result of a surgical risk assessment: erosion complications are a known mesh risk, and erosions in the bowel are much more deleterious that corresponding

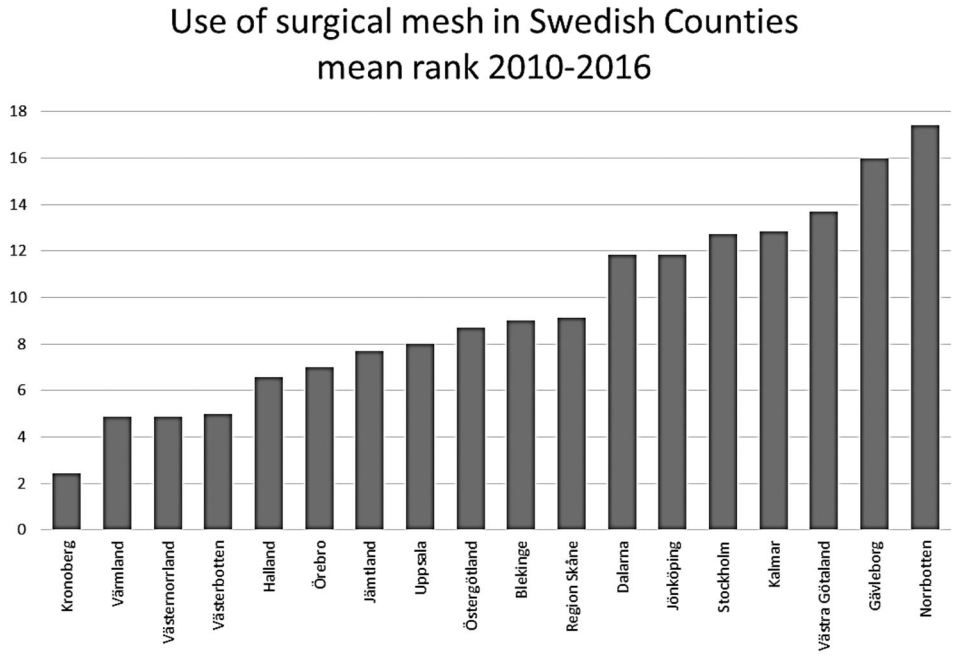

Figure 4. Mesh use: Mean rank of eighteen Swedish counties from 2010 to 2016 (Yearly ranking, lowest yearly rank in mesh use = 1; highest rank = 18).

Table 1. Initial model.

	B	S.E.	Wald	df	Sig.	Exp(B)
Degree of prolapse	0.241	0.035	47.064	1	0.000	1.273
Age	–0.011	0.006	3.753	1	0.053	0.989
Compartment split (Front(1))	0.553	0.204	7.355	1	0.007	1.739
Sexually active (No(1))	0.023	0.123	0.034	1	0.853	1.023
BMI	0.007	0.014	0.259	1	0.611	1.007
Number of vaginal deliveries	0.025	0.047	0.286	1	0.592	1.025
Constant	-0.092	0.554	0.027	1	0.869	0.913

Table 2. Reduced model.

	B	S.E.	Wald	df	Sig.	Exp(B)
Degree of prolapse	0.262	0.03	76.968	1	0.000	1.3
Age	–0.013	0.005	8.332	1	0.004	0.987
Compartment split (Front(1))	0.74	0.19	15.223	1	0.000	2.096
Constant	0.118	0.332	0.127	1	0.722	1.126

Note: Nagelkerke R^2: 0.061.

Table 3. Reduced model including year of surgery.

	B	S.E.	Wald	df	Sig.	Exp(B)
Degree of prolapse	0.258	0.03	72.151	1	0.000	1.294
Age	–0.012	0.005	6.567	1	0.010	0.988
Compartment split (Front(1))	1.128	0.199	32.209	1	0.000	3.09
Year of surgery (2016 is contrast)		82.838	6	0.000		
2010	1.096	0.177	38.132	1	0.000	2.991
2011	0.859	0.174	24.391	1	0.000	2.361
2012	0.657	0.169	15.041	1	0.000	1.93
2013	–0.071	0.165	0.184	1	0.668	0.932
2014	0.196	0.163	1.445	1	0.229	1.216
2015	–0.006	0.172	0.001	1	0.970	0.994
Constant	–0.699	0.366	3.643	1	0.056	0.497

Note: Nagelkerke R^2: 0.112.

Table 4. Reduced model including year of surgery and level of care.

	B	S.E.	Wald	Df	Sig.	Exp(B)
Degree of prolapse	0.272	0.031	77.807	1	0.000	1.312
Age	–0.013	0.005	7.731	1	0.005	0.987
Compartment split (Front(1))	1.087	0.2	29.626	1	0.000	2.964
Year of surgery (2016 is contrast)		81.32	6	0.000		
2010	1.091	0.178	37.622	1	0.000	2.976
2011	0.847	0.174	23.571	1	0.000	2.332
2012	0.653	0.17	14.729	1	0.000	1.920
2013	–0.065	0.165	0.157	1	0.692	0.937
2014	0.185	0.164	1.276	1	0.259	1.203
2015	–0.011	0.172	0.004	1	0.951	0.990
University hospital (Yes(1))	0.479	0.139	11.811	1	0.001	1.614
Constant	–1.01	0.38	7.069	1	0.008	0.364

Note: Nagelkerke R^2: 0.119.

Table 5. Reduced model including year of surgery, level of care and regions.

	B	S.E.	Wald	df	Sig.	Exp(B)
Degree of prolapse	0.279	0.032	77.723	1	0.000	1.321
Age	–0.012	0.005	6.357	1	0.012	0.988
Compartment split (Front(1))	1.04	0.201	26.843	1	0.000	2.829
Year of surgery (2016 is contrast)		77.892	6	0.000		
2010	1.068	0.181	34.632	1	0.000	2.909
2011	0.839	0.178	22.26	1	0.000	2.315
2012	0.705	0.174	16.408	1	0.000	2.024
2013	–0.018	0.169	0.011	1	0.917	0.983
2014	0.159	0.167	0.904	1	0.342	1.172
2015	–0.042	0.176	0.057	1	0.811	0.959
University hospital (Yes(1))	0.434	0.144	9.021	1	0.003	1.543
Regions			66.528	5	0.000	
Constant	–1.01	0.38	7.069	1	0.008	0.364

Note: Nagelkerke R^2: 0.158.

Table 6. Reduced model including year of surgery, level of care and counties.

	B	S.E.	Wald	df	Sig.	Exp(B)
Degree of prolapse	0.34	0.035	94.087	1	0.000	1.405
Age	–0.013	0.005	6.602	1	0.010	0.987
Compartment split (Front(1))	1.163	0.217	28.768	1	0.000	3.2
Year of surgery (2016 is contrast)		92.748	6	0.000		
2010	1.245	0.196	40.283	1	0.000	3.472
2011	1.166	0.195	35.831	1	0.000	3.21
2012	1.054	0.189	30.975	1	0.000	2.87
2013	0.103	0.18	0.324	1	0.569	1.108
2014	0.203	0.178	1.299	1	0.254	1.226
2015	0.154	0.189	0.663	1	0.415	1.166
University hospital (Yes(1))			276.273	19	0.000	
Regions	0.34	0.035	94.087	1	0.000	1.405
Constant	–0.013	0.005	6.602	1	0.010	0.987

Note: Nagelkerke R^2: 0.304.

lesions in the bladder. This risk difference is arguably the reason for some caution to use mesh in the back compartment.

Geography is by far the most important parameter when it comes to explaining the use of mesh in Sweden.

Evidence-based decision-making is one of the core values of any health care organisation. Deciding between different treatment options is supposed to be a rational process. Yet, Swedish surgeons, unaltered through 7 years, have made mesh decisions in a clearly biased fashion, highly influenced by geographical factors, and with no measurable change towards national consensus.

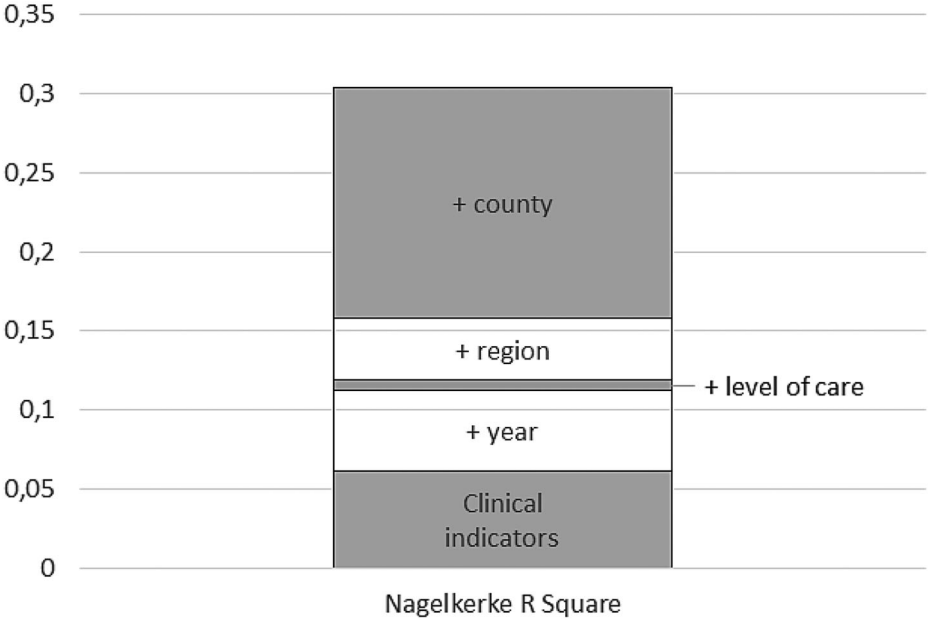

Figure 5. Contribution of parameters: The percentage of the total variation that is explained by the analysed parameters.

In the first years of our observation period, progress was dependent on surgical 'learning by doing.' Today, more information is available than most surgeons can absorb single-handedly. Our results indicate that different decision makers have drawn different conclusions from the available information.

Such early decisions have led to obvious 'communities of practice' at the county and region levels, where the proportion of patients assumed to benefit from mesh applications have remained unchanged over time. Counties and regions continued to use mesh in roughly the same manner, maintaining the disparities between the entities. Even the FDA warning led only to a general lowering of mesh application but the pattern remained unchanged. From the patient's perspective, this represents a kind of geographical lottery whether mesh is used or not.

Within the scope of this article, we do not intend to argue whether the use of mesh in POP operations should be low or high. However, with the application of mesh on county level ranging from 7% to well beyond 90%, the large regional variation in surgeons' choices is due to impact negatively on clinical care, as a great part of these decisions must be suboptimal.

Optimisation is rarely possible in real life (Simon, 1991) and people use different heuristics to reach decisions (Marewski & Gigerenzer, 2012). This bounded rationality is obvious in medical decision-making and in our study case: authorities and surgeons should acknowledge that and the possibility of error as a first step towards erring less.

It has previously been demonstrated that clinical decision-making is subject to cognitive biases (Croskerry, 2002, 2013). While we have not examined the actual decision-making process, the fact that Swedish surgeons' decision-making patterns across counties and health care regions have remained unchanged, suggests that Swedish surgeons', in conditions were available scientific information is either ambiguous, inconsistent, or simply overwhelming, tend to be biased by geographical factors. They seem to be biased by geographical communities of practices as per how to interpret existing evidence regarding the effectiveness of mesh. The extraordinary disparity in mesh use, shown in a survey of 15 OECD countries (Haya et al., 2015), indicates that this is by no means a Swedish problem alone, but an international challenge.In the case of POP, where surgeons have their own experiences with the conditions under which mesh is useful or not, this may make them susceptible to favoring information that supports their own, prior hypotheses. In line with this, studies on clinical judgment and decision-making have shown that many people have an illusion of validity (Christensen-Szalanski & Bushyhead, 1981; Einhorn & Hogarth, 1978; Tversky & Kahneman, 1974). Several other psychological biases, well-documented in the medical world (Arkes, 1981; Arkes, Wortmann, Saville, & Harkness, 1981) could explain the tendency to rely too heavily on the first piece of information when making a decision, or the tendency to stick with default options when given a choice (e.g. Hindsight bias (Fischhoff, 2003), Framing effect (Mazur & Hickam, 1990), and Lower tolerance to risk (Saposnik, Redelmeier, Ruff, & Tobler, 2016)). This could explicate the creation of 'norms' within the geographical areas that we observe in the POP in Sweden.

All the aforementioned cognitive biases may lead to diagnostic errors and suboptimal management of diseases. In a metaanalytical study by Saposnik et al. (2016) results were striking – overconfidence, lower tolerance to risk, the anchoring effect, and information and availability biases were associated with diagnostic inaccuracies in 36.5 to 77% of case-scenarios. Further, five out of seven (71.4%) studies showed an association between cognitive biases and therapeutic or management errors.

A limitation of the study is the risk of confounding because prolapse operations have many levels of difficulty, ranging from simple procedures in day surgery to very advanced operations and unsolved reconstructive problems. In order to evaluate surgeons' decision-

making, it is necessary to select groups with comparable patients to avoid confounding. To minimise this challenge, we created a largely homogenous group of patients by careful selection: Anterior or posterior colporrhaphy are the most common operations in prolapse surgery and use of mesh in recurrent operation is internationally accepted. We also included only healthy patients with no other concurrent operations and excluded small, specialised clinics. This selection results in a group of comparable patients, avoiding confounding by special anatomic or operative technical necessities.

Another limitation is that we do not have the means of examining actual decision-making of the surgeons. Instead, in an exploratory manner, we test the influence that different factors have in explaining surgical outcomes. Future studies should test the way that decision makers actually behave and examine these processes in a more qualitative and controlled way.

After more than a decade of mesh use, it is probably too late for an evaluation of mesh in general to have desirable effect. Extraordinary disparity in mesh use between OECD countries shows that this is an international challenge (Haya et al., 2015). It seems that the use of mesh in POP is no longer perceived as experimental. Too many surgeons use too many different types of mesh in too many different anatomical sites with too many different techniques, combined with a steady flow of new types of mesh to replace retracted ones – without clear evidence of their safety and efficacy (Wall & Brown, 2010). After widespread adoption, it has been proposed to use large observational national and regional studies as the main tools for evaluation of patient selection, practice, and outcomes of surgery (Ergina et al., 2009). Therefore, a possible way forward may be to start a process of developing agreed and complied regional, or even national, guidelines for the use of specific types of mesh in defined types of POP operations, combined with long-term surveillance and evaluation by quality registers.

Ethics

The GynOp registry is approved by the Ethics Committee of the University of Umeå, Umeå, Sweden (Dnr 04–107). This study and the use of data from the register were approved by the Ethics Committee, University of Umeå, Sweden (Dnr 08–076 M).

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No potential conflict of interest was reported by the authors.

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