Orthopaedica Belgica Digital Congress 24 April 2021

The past and today creates the future; The promise of health care registers

Peter Fritzell, register manager Swedish national quality register "Swespine" Swedish Society of Spinal Surgeons (4s), RKC Stockholm, and Futurum Academy Jönköping, Sweden

- Background Historical perspective
- 7 examples on how register data can be used

I will address seven examples, all based on national quality registers, and the ultimate question is; "what's in it for me/us!"

- **1.** Are we surgeons getting better with time? Swespine
- 2. "Register effect" on a specific diagnosis Lumbar spinal stenosis? Swespine
- **3.** "Register comparison" in incidence and outcome between countries. Swespine-NorSpine-Danespine (Sweden-Norway-Denmark)
- 4. When on a time line is a lumbar disorder costly? Swespine
- 5. Value based reimbursement. Swespine
- 6. Case-mix adjustment. Swespine
- 7. "The Dialogue Support". Swespine; <u>www.eurospine.org</u>

• Background – Historical perspective

Who am I, an orthopedic spine surgeon

- third generation of spine surgeons 1985....
 (since Mixter and Barr 1934....)
- Register manager for the national Swedish spine register, Swespine", since 1998.
- What have I/we learned a long journey, many "dead ends".... for example - don't use physicians in registering - they should analyse data!
- Consequence analyses are often missing

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- I know that securing and improving quality of care, and research, benefits from registering
- I know that relevant international cooperation can be based on registers
 - I am convinced that Eurospine can play an important role
 - I am convinced that registers and cost-effectiveness evaluations is the way forward for the profession to regain the initiative in "health care questions"



Level of evidence – the past (today)





Florence Nightingale, Amory Codman*, Archie Cochrane

Where/when did they get their "inspiration"?



1820-1910 Crimean war 1853-56 **1869-1940** First world war 1914-1919 **1906-1988** Second world war 1939-1945

Ethical approval.....

Peter Fritzell, Swespine 210424

The end result idea* - 1914

Ernest Amory Codman* 1869-1940 *Clinical outcome* "The Shoulder" 1934 Sarcoma register 1920

Florence Nightingale

1820 – 1910 Crimean war 1853-1856 *Mortality*



1917;

"I am considered eccentric, because I say publicly that if the hospitals want to be sure to get better, then they need to find out what results they have. They have to analyze their results to find strengths and weaknesses. **They need to compare their results with others.** <u>Such choices will not be eccentric in a few years.</u> " **100 years later – the end result idea...**

We stand on her shoulders.....

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The future – we lean on the past

We rely on;

Clinical experience Comparisons Trial and error **Clinical expertise** In my hands **Observational studies Retrospective studies Prospective studies** RCT Reviews Meta-analyses Registers Industry

Problems;

Subjective - bias - confounders Different baseline variables Different outcome variables Different populations Small population samples Different Diagnoses Different treatments Confounders Biases Industry Profit

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Level of evidence – today and in the Future



The end result idea - consequence analysis!



Peter Fritzell, Swespine 210424



The end result idea - consequence analysis!



Peter Fritzell, Swespine 210424

What is a register? Prospective collection of data – and can therefore be used in an "observational study"

The first (sic) "modern" register in Health care was Norwegian (sic), 200 years ago - Lepra

Register are used in other disciplines for thousands of years f ex in Astronomy

Register study = Observational study vs. RCTs

Can register data be trusted?

Yes - if adequate statistical analyses are used; STROBE

Special Articles

A COMPARISON OF OBSERVATIONAL STUDIES AND RANDOMIZED, CONTROLLED TRIALS

KJELL BENSON, B.A., AND ARTHUR J. HARTZ, M.D., PH.D.

A COMPARISON OF OBSERVATIONAL STUDIES AND RANDOMIZED, CONTROLLED TRIALS

KJELL BENSON, B.A., AND ARTHUR J. HARTZ, M.D., PH.D. N Engl J Med 2000;342 1878-86

ABSTRACT

Background

For many years it has been claimed that observational studies find stronger treatment effects than randomized, controlled trials. We compared the results of observational studies with those of randomized, controlled trials.

Methods

We searched the Abridged Index Medicus and Cochrane data bases to identify observational studies reported between 1985 and 1998 that compared two or more treatments or interventions for the same condition. We then searched the Medline and Cochrane data bases to identify all the randomized, controlled trials and observational studies comparing the same treatments for these conditions. For each treatment, the magnitudes of the effects in the various observational studies were combined by the Mantel–Haenszel or weighted analysis-of-variance procedure and then compared with the combined magnitude of the effects in the randomized, controlled trials that evaluated the same treatment.

Results

There were 136 reports about 19 diverse treatments, such as calcium-channel–blocker therapy for coronary artery disease, appendectomy, and interventions for subfertility. In most cases, the estimates of the treatment effects from observational studies and randomized, controlled trials were similar. In only 2 of the 19 analyses of treatment effects did the combined magnitude of the effect in observational studies lie outside the 95 percent confidence interval for the combined magnitude in the randomized, controlled trials.

Conclusion

We found little evidence that estimates of treatment effects in observational studies reported after 1984 are either consistently larger than or qualitatively different from those obtained in randomized, controlled trials.

RCT ≈ **Observational studies** ≈ **Register studies**

<u>1. Benson K¹</u>, <u>Hartz AJ.</u> **A comparison of observational studies and randomized, controlled trials.** <u>N Engl J. Med.</u> 2000 Jun 22;342(25):1878-86.

2. <u>Concato J</u>, <u>Lawler EV</u>, <u>Lew RA</u>, <u>Gaziano JM</u>, <u>Aslan M</u>, <u>Huang GD</u>. **Observational methods in comparative effectiveness research.** <u>Am J Med.</u> 2010 Dec;123(12 Suppl 1)

3. <u>Concato J</u>1, <u>Shah N</u>, <u>Horwitz RI</u>. **Randomized, controlled trials, observational studies, and the hierarchy of research designs.** <u>N Engl J Med.</u> 2000 Jun 22;342(25):1887-92.

<u>4.</u> Colditz GA</u>. Overview of the epidemiology methods and applications: strengths and limitations of observational study designs. <u>Crit Rev Food Sci Nutr.</u> 2010;50 Suppl 1:10-2.

5. Jacobs WC et al. Spine surgery research: on and beyond current strategies. Spine J 2012.

<u>6. Phillips et al.</u> Lumbar spine fusion for chronic low back pain due to degenerative disc disease: a systematic review. Spine 2013.

• Swespine - continous annual reports : 1 year FU of patients operated on 2012; http://www.4s.nu/4s-f%C3%B6rening/%C3%A5rsrapporter-swespine-42017503

Registers – in order to be useful;

"what's in it for me/us!"

Who are "me"/us?

- Therapists
- The staff
- Administrators
- Secretaries
- Politicians
- Patients
- The public
- Scientists
- Risk capitalists.....
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What makes a register useful? ADEQUATE;

- 1. aims
- 2. agreed upon variables
- 3. collection of data
- 4. coverage, completeness and FU
- 5. analyses
- 6. reporting
- 7. daily practice willingness to change

Ultimate keys

- Simplicity
- Daily practice
- What's in it for me/us
- Consequence analyses
- Willingness to change practice

SIMPLICITY = compliance

a register is not a clinical study, although it can be used in such studies!

Registers in Sweden

In 2021 > 100 registries funded by the government

Boston Consulting Group 2011

- "Sweden has the most cost-effective health care in the world"
- It's because of their use of registers
- Effect; 32 million EUROS/year for 5 years to health care registers, 2012-2016
- > 100 national quality registers in Sweden

Swespine

relevance on a national level

<u>Coverage</u> = n. clinics registering

<u>Completeness</u> = patients registered at the time of Index procedure

Follow up = patients followed up after 1 - 2 - 5 - 10 years.....



Swespine

relevance on a <u>national level</u>

<u>Coverage</u> = >95%

Completeness = 85%

<u>Follow up > 70%</u>



• Results based on using Swespine

- apart from over 120 scientific studies published in international journals

Registers – "what's in it for me/us!"

Seven examples based on national spine registers

1. Are we surgeons getting better with time? <u>Swespine</u>

- 2. Effect on a specific diagnosis Lumbar spinal stenosis. *Swespine*
- 3. Comparison in incidence and outcome between countries. Swespine-NorSpine-Danespine
- 4. When on a time line is a lumbar disorder costly, and what are the costs after surgery. <u>Swespine</u>
- 5. Case-mix adjustment. Swespine
- 6. Value based reimbursement. <u>Swespine</u>
- 7. "The Dialogue Support". Swespine; www.eurospine.org

One year results after **fusion for CLBP 2003-2011/Swespine**

All kind of fusion procedures – are we getting better?



Registers – "what's in it for me/us!"

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N of Lumbal Spinal Stenos <u>with olisthesis >3mm</u> – surgical procedure



N of Lumbal Spinal Stenos with olisthesis >3mm – surgical procedure Swespine data **Changes in surgical practice in Sweden during the last 15 years**

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Peter Fritzell, Swespine 210424

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From The Swedish Spine Register, Sweden _ SPINE Patients with and without olisthesis

Does fusion improve the outcome after decompressive surgery for lumbar spinal stenosis? A register study based on Swespine

A TWO-YEAR FOLLOW-UP STUDY INVOLVING 5390 PATIENTS

Whether to combine spinal decompression with fusion in patients with symptomatic lumbar spinal stenosis remains controversial. We performed a cohort study to determine the effect of the addition of fusion in terms of patient satisfaction after decompressive spinal surgery in patients with and without a degenerative spondylolisthesis.

The National Swedish Register for Spine Surgery (Swespine) was used for the study. Data were obtained for all patients in the register who underwent surgery for stenosis on one or two adjacent lumbar levels. A total of 5390 patients fulfilled the inclusion criteria and completed a two-year follow-up. Using multivariable models the results of 4259 patients who underwent decompression alone were compared with those of 1131 who underwent decompression and fusion. The consequence of having an associated spondylolisthesis in the operated segments pre-operatively was also considered.

At two years there was no significant difference in patient satisfaction between the two treatment groups for any of the outcome measures, regardless of the presence of a preoperative spondylolisthesis. Moreover, the proportion of patients who required subsequent further lumbar surgery was also similar in the two groups

In this large cohort the addition of fusion to decompression was not associated with an improved outcome.



A Randomized, Controlled Trial of Fusion Surgery for Lumbar Spinal Stenosis

Peter Försth, M.D., Ph.D., Gylfi Ólafsson, M.Sc., Thomas Carlsson, M.D., Anders Frost, M.D., Ph.D., Fredrik Borgström, Ph.D., Peter Fritzell, M.D., Ph.D., Patrik Öhagen, Karl Michaëlsson, M.D., Ph.D., and Bengt Sandén, M.D., Ph.D.

Randomized, Controlled Trial of Fusion Surgery for Lumbar Spinal Stenosis NEJM 2016 Apr 14;374(15):1413-23.

Methods: We randomly assigned 247 patients between 50 and 80 years of age who had lumbar spinal stenosis at one or two adjacent vertebral levels to undergo either decompression surgery plus fusion surgery (fusion group) or decompression surgery alone (decompression-alone group). Randomization was stratified according to the presence of preoperative degenerative spondylolisthesis (in 135 patients) or its absence.

Results: There was no significant difference between the groups in the mean score on the ODI at 2 years (27 in the fusion group and 24 in the decompression-alone group, P=0.24) or in the results of the 6-minute walk test (397 m in the fusion group and 405 m in the decompression-alone group, P=0.72). **Results were similar between patients** with and those without spondylolisthesis. Among the patients who had 5 years of follow-up and were eligible for inclusion in the 5-year analysis, there were no significant differences between the groups in clinical outcomes at 5 years.

Conclusion: Among patients with lumbar spinal stenosis, with or without degenerative spondylolisthesis, <u>decompression surgery plus fusion surgery did not result in better clinical outcomes at 2 years and 5 years</u> than did decompression surgery alone.

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The national surgical spine registers in Sweden, Denmark and Norway 2011-13

	Coverage*	Completeness**	Follow up 1 year***	
Swespine	90%	75%	70%	
DaneSpine	80%	62%	57%	
NORspine	93%	60%	66%	

*Coverage; nr of clinics reporting to the register/nr of clinics performing spine surgery in the country **Completeness; nr of patients registered at baseline/nr of patients actually operated at baseline ***Follow up; nr patients registered at 1 year FU/nr of patients registered at baseline

Sweden; Completeness = number of patients in Swespine (<u>www.swespine.se</u>)/number of patients in the official PAR register administered by the The National Board of Health and Welfare (<u>http://www.socialstyrelsen.se/English</u>)

Denmark;

Norway;



	Sweden	Denmark	Norway	Total
Baseline	7,389	3,661	3,173	14,223
1 year FU	5,990 (81%)	2,341 (64%)	2,559 (81%)	10,890 (77%)

- Outcome was similar in the three countires, irrespectively of case-mix adjustment, and irrespectively of arthrodesis

- Surgical incidence varied considerably, as well as concomittant fusion

Smoking - Duration of pain - Born outside EU were negative factors

Key question; Cost - effectiveness

Lumbar spinal stenosis: comparison of surgical practice variation and clinical outcome in three national spine registries

Greger Lønne, MD, PhD; Peter Fritzell, MD, PhD, Olle Hägg, MD, PhD, Dennis Nordvall, MStat, Paul Gerdhem, MD, PhD, Tobias Lagerbäck, MD, Mikkel Andersen, MD, Søren Eiskjaer, MD, Martin Gehrchen, MD, PhD, Wilco Jacobs, MSc, PhD, Miranda L. van Hooff, MSc, PhD, Tore K. Solberg, MD, PhD

Spine J. 2019 Jan;19(1):41-49.

Effectiveness of surgery for sciatica with disc herniation is not substantially affected by differences in surgical incidences among three countries: results from the Danish, Swedish and Norwegian spine registries

Tobias Lagerbäck, Peter Fritzell, Olle Hägg, Dennis Nordvall, Greger Lønne, Tore K. Solberg, Mikkel Ø. Andersen, Søren Eiskjær, Martin Gehrchen, Wilco C. Jacobs, Miranda L. van Hooff, Paul Gerdhem

Eur Spine J. 2019 Nov;28(11):2562-2571.

Surgical Treatment of Degenerative Disk Disease in Three Scandinavian Countries: An International Register Study Based on Three Merged National Spine Registers

Mikkel Østerheden Andersen, MD, Peter Fritzell, MD, PhD, Søren Peter Eiskjaer, MD, Tobias Lagerbaeck, MD, Olle Hagg, MD, PhD, Dennis Nordvall, MSc, Greger Lönne, MD, Tore Solberg, MD, PhD, Wilco Jacobs, MSc, PhD, Miranda van Hooff, MSc, PhD, Paul Gerdhem, MD, PhD, and Martin Gehrchen, MD, PhD **Global Spine J. 2019 Dec;9(8):850-858.**

Registers – "what's in it for me/us!"

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- 7. "The Dialogue Support". Swespine; www.eurospine.org

Health economic pathway in patients with low back pain using five national registers to monitor costs

Profile of Low Back Pain: Treatment and Costs Associated With Patients Referred to Orthopaedic Specialists in Sweden. Jonsson E¹, Olafsson G, Fritzell P, Hägg O, Borgström F. Spine 2017, Jan 31

Total cost (1000 Euro) per month, <u>24 months before and after</u> Index-point * = seeing an orthopedic specialist.

Five national registers; Swespine, Vega (Regional Register), Swedish drug prescription, Patient Administrative Register (PAR), Swedish Social Insurance Agency Register



Registers – "what's in it for me/us!"

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Swespine annual report 2013; Central Spinal Stenosis (>50% of all spine procedures)

Patient reported improvement/clinic (Global assessment CSS) **Does case-mix adjustment make any difference? Funnel plot illustration**



http://www.4s.nu/Homepage/Download-File/f/1265399/h/2716eb57e403a90c6b4cae6a57885bba/Report 2012 swespine englishversion

Swespine annual report 2013; Central Spinal Stenosis (>50% of all spine procedures)

Patient reported improvement/clinic (Global assessment CSS) **Case-mix adjustment makes a difference! Funnel plot illustration**



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VBC – Value Based Care in Europe; OECD January 2017

Organisation for Economic Co-operation and Development. https://www.oecd.org/els/health-systems/health-care-quality-and-outcomes.htm



VBR – Value Based Reimbursement on three private clinics in Sweden since 2013

Registers – "what's in it for me!"

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Variables included in Swespine – "different mix" for different patients

Variables included in <u>Degenerative lumbar spinal</u> <u>disorders</u> (LDH, LSS, DDD)

Diagnose Type of clinic (University, County hospital, Private clinic) Age Gender Work status Sick pension Retention pension Smoking Quality of life (EQ5D) Walking distance Pain duration LEG Pain duration BACK Preop pain LEG (NRS) Preop pain BACK (NRS) Function (ODI)How was your spine procedure financed? Comorbidity

Are you active in sports? What do you think of your possibilities to return to work? How physical is your current workload? Are you out of work? Since how long have you been unable to work? Type of previous spine procedure Acute or Elective surgery Type of procedure/Index operation How many previous spine procedures? Do you take pain killers for your back/leg pain? Type of instrumentation Type of implant Type of bone transplant Operated from the left/right Antibiotic prophylaxis Postop complications Reoperation during Index stay Type of reop procedure Peter Fritzell, Swespine 210424 Number of reop 62

Variables used for "case-mix adjustment" in Swespine/the Dialogue support

These variables have been identified, after statistical analyses, as predictive of patient reported outcome one year after surgery for the following **Degenerative lumbar spinal disorders**; LDH, LSS, DDD

1. Diagnosis

2. Type of clinic (University, County hospital, Private clinic)

3. Age

4. Gender

5. Work status

6. Sick pension

7. Retention pension

8. Smoking

9. Quality of life (EQ5D)

10. Comorbidity

11. Walking distance

12. Pain duration LEG (months)

13. Pain duration BACK (months)

14. Preop pain LEG (NRS)

15. Preop pain BACK (NRS)

16. Function (ODI)

Spine surgery – discussion with the patient

The "Dialogue support" www.eurospine.org

A prediction tool based on data from the Swedish national quality spine register;

Swespine

Peter Fritzell/register manager Swespine



i 🔒 Dialogue support for spine surgery - based on Swespine, the Swedish Spine Register RESULTS • 0 Basic information Back-specific information Proportion satisfied patients Expected length of stay Proportion with successful outcome Subgroup 81 % 77 % 1.6 days Diagnosis group Spinal Stenosis w Satisfied with outcome Date of discharge – date of surgery Pain completely resolved or greatly improved 1 2 3 4 5+ Operated levels Clinical department type (only length of University \mathbf{w} o 🕤 🙆 PROPORTION WITH SUCCESSFUL OUTCOME = PAIN COMPLETELY RESOLVED OR SIGNIFICANTLY IMPROVED AFTER ONE YEAR (GREEN AND LIGHT GREEN) stay) Sociodemographics Pain free Much improved Slightly improved Unchanged Worse 70 Age · · · · · <u>·</u> · · · · <u>·</u> Gender Man \mathbf{w} 6,78 % 13,08 % Unemployed 43,94 % Disability pension No \mathbf{w} 32,97 % Retirement pension No Health profile Smoker Previous spine surgery • • DESCRIPTION 0.4 Quality of life (EQ-5D) Comorbidity* Back-specific information 201008_PF_The D....pptx ^ 201008_PF_The D....pptx ^ 201008_PF_The D....pptx ^ 201009_Dialogue s....pdf ^ 🔨 2017_CORR_2104....docx 🔨 2017_CORR_2104....docx ^ Visa alla × 17:45 ∧ ⓒ 촠 맏 ◁_× 돶 ________ 0 Ξŧ ÷ 騔 \mathbf{O} 83

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Dialogue support for spine surgery - based on Swespine, the Swedish Spine Register







i 🔒 Dialogue support for spine surgery - based on Swespine, the Swedish Spine Register RESULTS - 0 Basic information Back-specific information Proportion satisfied patients Expected length of stay Proportion with successful outcome Subgroup 80 % 74 % 2.5 days Diagnosis group Spinal Stenosis Ŧ Satisfied with outcome Pain completely resolved or greatly improved Date of discharge - date of surgery 1 2 3 4 5+ Operated levels Clinical department type (only length of University \mathbf{w} 🛆 🖨 🧭 PROPORTION WITH SUCCESSFUL OUTCOME = PAIN COMPLETELY RESOLVED OR SIGNIFICANTLY IMPROVED AFTER ONE YEAR (GREEN AND LIGHT GREEN) stay) Sociodemographics Pain free Much improved Slightly improved Unchanged Worse 70 Age 3.83 Gender Woman 7,60 % 14,08 % 40.91 % Unemployed Disability pension No w 33,58 % Retirement pension No Health profile Smoker Previous spine surgery • • DESCRIPTION 0.3 Quality of life (EQ-5D) -0.59 -0.19 -0.21 -0.5 Proportion satisfied patients Proportion with successful outcome Expected length of stay (pain completely resolved or greatly improved) Comorbidity* The proportion of satisfied patients has been calculated at: 80 % Proportion of patients with a successful outcome is calculated to be: 74 % Average length of stay is : 2.5 days for patients with the selected profile. for patients with the selected profile for patients with the selected profile Back-specific information Question in Swespine: Question in Swespine: Question in Swespine: What is your attitude to the outcome of your spine surgery? How would you rate your leg pain/sciatica today compared with prior to surgery? Date of Surgery, Date of Discharge 220419_The Dial....docx ^ 210401_Björn Lin....docx æ æ æ 220419_The Dial....docx 🖻 förslag stadgeänd....doc \land sjösättningsordnin....pdf Report_2012_swes....pdf ^ Visa alla X sjösättningsordnin....pdf 🔨 🔨 ~ へ 違 📥 臣 🗤 😻 14:54 O Skriv här för att söka 馰 0 **H** ÷



i 🔒 Dialogue support for spine surgery - based on Swespine, the Swedish Spine Register RESULTS • 0 Basic information Back-specific information Proportion satisfied patients Expected length of stay Proportion with successful outcome Subgroup 52 % 48 % 2.6 days Diagnosis group Spinal Stenosis Satisfied with outcome Pain completely resolved or greatly improved Date of discharge - date of surgery 1 2 3 4 5+ Operated levels Clinical department type (only length of University Ŧ 🛆 🖨 🧭 PROPORTION WITH SUCCESSFUL OUTCOME = PAIN COMPLETELY RESOLVED OR SIGNIFICANTLY IMPROVED AFTER ONE YEAR (GREEN AND LIGHT GREEN) stay) Sociodemographics Pain free Much improved Slightly improved Unchanged Worse 70 Age Gender Woman 14,61 % 17,17 % Unemployed 16,72 % Disability pension 30,48 % No w 21.01 % Retirement pension No Health profile Smoker Previous spine surgery • • DESCRIPTION 0.3 Quality of life (EQ-5D) -0.59 -0.19 0.21 0.4 4 Proportion satisfied patients Proportion with successful outcome Expected length of stay (pain completely resolved or greatly improved) Comorbidity' The proportion of satisfied patients has been calculated at: 52 % Proportion of patients with a successful outcome is calculated to be: 48 % Average length of stay is : 2.6 days for patients with the selected profile. for patients with the selected profile for patients with the selected profile Question in Swespine: Question in Swespine: Question in Swespine: What is your attitude to the outcome of your spine surgery? How would you rate your leg pain/sciatica today compared with prior to surgery? Date of Surgery, Date of Discharge 220419_The Dial....docx 🔷 210401_Björn Lin....docx æ æ æ 220419_The Dial....docx 🖻 förslag stadgeänd....doc \land sjösättningsordnin....pdf sjösättningsordnin....pdf Report_2012_swes....pdf ^ Visa alla X ~ へ 6 📥 🏪 🗤 😻 14:53 2021-04-22 O Skriv här för att söka 馰 0 **H** ÷



Thank you

LSS + olistesis > 3mm.

% Success after 1 year; PROM - Global assessment (Pain free + Much better)

<u>Similar results – see OBS below;</u>

OBS! Observational raw data – not adjusted for case-mix ("different populations")

Dekompression + Fusion = GREY vs. Dekompressi



Five questions to be answered

- Why
- What
- Who
- When
- HOW