8. September NKR

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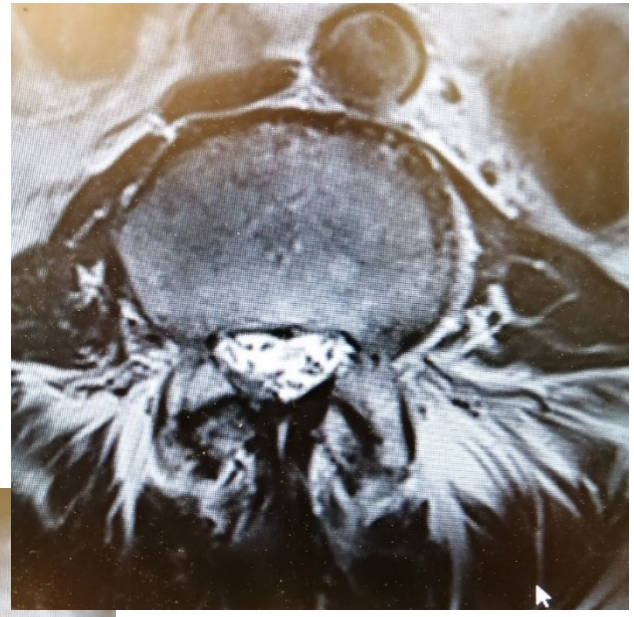
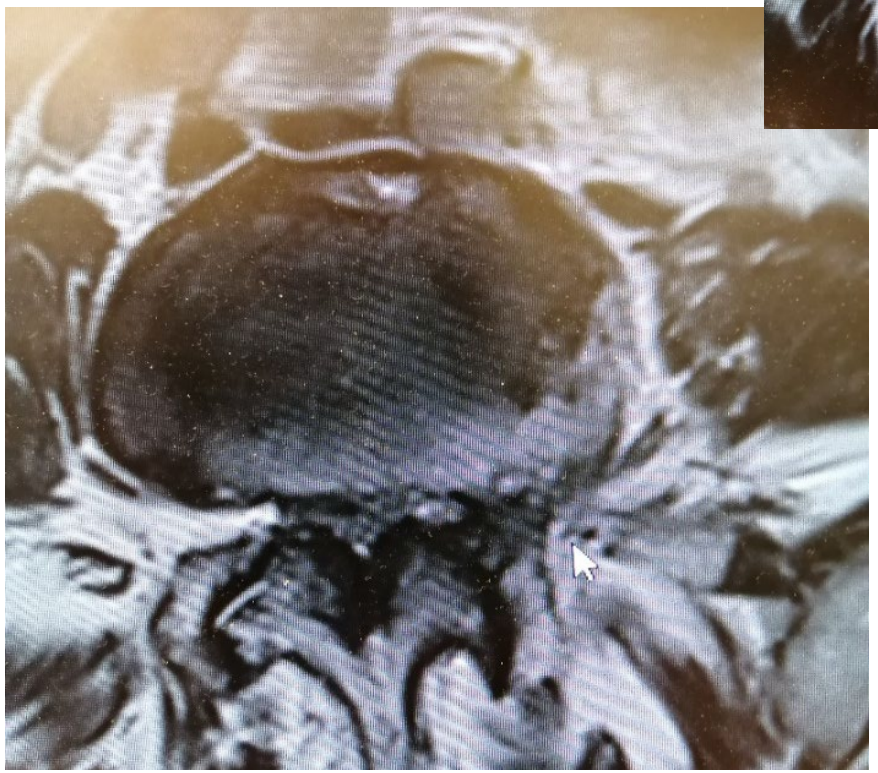
NTNU

Nasjonalt Kvalitetsregister for Ryggkirurgi
Degenerativ rygg

Spinal stenose



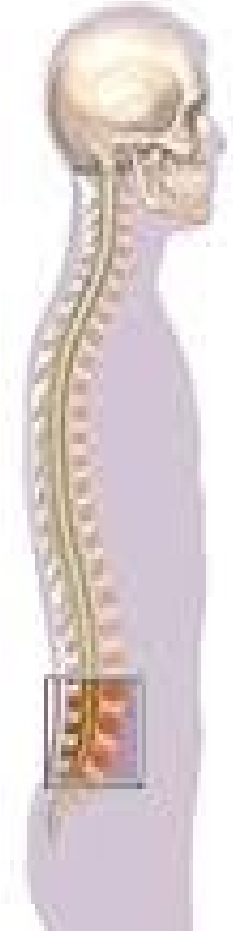


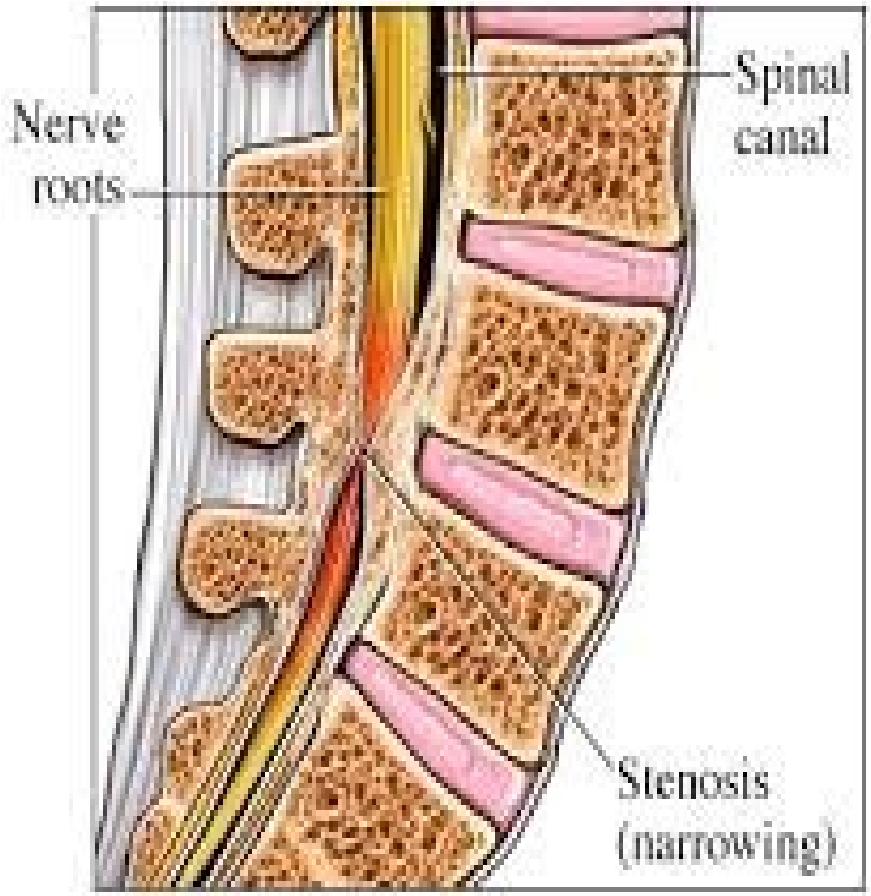
Lumbal spinal stenose

- Prevalens ~10%
- NORspine: 2000/år

- Kirurgi 60-80% god effekt
-
- 50 000 NOK/opr
- Komplikasjoner

- Teknikk
- **SELEKSJON**

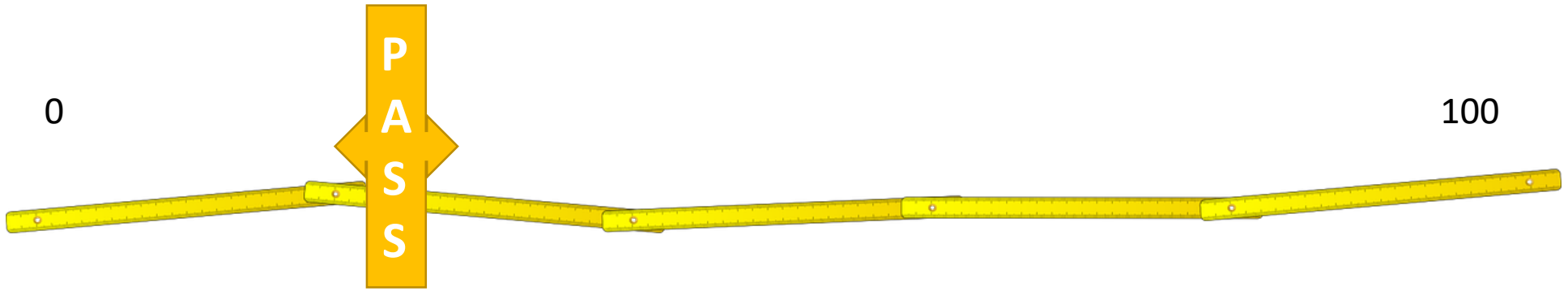




Kirurgi for smerter – hvordan måle resultatet?

PROM
NRS /VAS
Oswestry Disability Index - ODI
EQ5D

Kan vi påvirke smerteopplevelsen ved å trygge / aktivere ? Uavhengig kirurgien



Patient Acceptable Symptom State

Minimum Clinical Important Difference (MCID)

Suksess kriterium

Registerforskning

styrker	svakheter
Data eksisterer	Datainnsamlet av andre, mangler variabler, feilklassifisert, vanskelig å etterprøve kvalitet
Store tall , n (hele populasjonen, dvs ikke selection bias, kan finne sjeldne kompl/hendelser	P verdi ikke intrersssant, effect estimate viktigere
Data innsamlet uavh og prospectivt	Missing data vanskelig, hva er grunnen til missing
Tid – oppfl allerede gjort	Datakvalitet kan være lav
Confoundere er registrert ofte	Left truncation ??
	Post hoc analyses

Oppsummering bakgrunn:

- Stagnasjon, andel failure ganske likt (30-38%) 2007-17, trass i teknisk utvikling. **Pasientseleksjon** er viktig fokusområde
- Suksess er definert inkl prediktorer – hva med **failure** ?
- Register - **datakvalitet**

- Min etappe:
  - Definere failure + worsening
  - Identifisere prediktorer

  - Sjekke datakvalitet

	Aim	Design	Population	Results/conclution
Study 1	What are the best cut offs in common PROMs to define failure after surgery for LSS?	Retrospective observational study using prospectively collected data. Anchor based method (ROC-analyses).	11873 patients operated for LSS between 2007-2017 and registered in NORspine. 8989 completed 12 mnths FU.	Failure: final ODI score >31, ODI change < 9 and ODI % change < 20% Worsening: final ODI score >36, ODI change < 4 and ODI %change < 9%
Study 2	How accurate is the NORspine registry ?	Cross-sectional study. Agreement quantified using kappa statistics and intraclass correlation coeffesient.	474 patients operated for LSS in 2015 and 2016 at four hostpitals in Norway	Surgical variables high accuracy, comorbidity and complications moderate to low accuracy
Study 3	Do the most common surgical complication (dural tear) affect the risk of failure ?	Retrospective observational study with prospectively collected data. Multivariate logistic regression analysis.	11873 patients operated for LSS in Norway between 2017-2017 and 8919 completed 12 months follow-up, 439 dural tears	Dural tear increases the odds of failure (OR) by 1.5.
Study 4	Identify predictors for failure after surgery or LSS	Retrospective observational study with prospectively collected data. Multiple logistic regression.	11873 patients operated for LSS between 2007-2017 and registered in NORspine.	Duration of symptoms OR=2,2 Former surgery OR=1,9 Age >70 OR=2,0 Socioeconocmic OR 1,4-1,6 General health OR 1,3 -1,4
Study 5	Do loss to follow up affect interpretation of the results in NORspine ?	Cross sectional study. Descriptive, Stud T	474 patients operated for LSS in 2015-2016, AHUS + SI	Non responders are younger, healthier and not native norwegians. Non responders have the same clinical outcome as responders
Study 6	Prevalence of post operative complicatinons in LSS surgery. Do post operative complications affect the risk of failure ?	retrospective observational study	474 patients operated for LSS in 2015+2016. Logistic regression	NORspine registradet complication in 15.6 %, EPR in 16%. No association between PO compl and failure / satisfaction

Table 1: Patient characteristics of 11873 Norwegian patients with surgically treated lumbar spinal stenosis.

	All patients, n=11873 Mean (95%CI), or n (%)	Failure (ODI>31), n= 2950 Mean (95%CI), or n (%)	Worsening (ODI>39), n= 1921 Mean (95%CI), or n (%)
Age (cont)	65.8 (65.6 – 66.0)	67.8 (67.2 – 68.0)	67.8 (67.3 – 68.3)
Age > 70 years	4442 (37.5%)	1352 (45.8%)	1016 (52.9%)
Gender female	6204 (52.3%)	1714 (58.1%)	1115 (58.0%)
Civil status, living alone	3169 (26.8%)	937 (31.9%)	619 (32.4%)
Native Norwegian speaker	11353 (96.0%)	2796 (95.4%)	1910 (95.3%)
ASA grade >2*	2462 (21.0%)	848 (29.1%)	601 (31.7%)
Body Mass Index (cont)	27.6 (27.5 – 27.7)	28.0 (27.9 – 28.2)	28.1 (27.9 – 28.3)
Body Mass Index >30	2920 (26.2%)	853 (31.1%)	573 (32.1%)
Smoking	2518 (21.4%)	682 (23.3%)	470 (24.7%)
Level of education below college	8209 (70.4%)	2281 (79.1%)	1501 (80.1%)
Any comorbidity	7243 (67.2%)	2031 (75.2%)	1347 (76.0%)
Receives Disability benefit (all types)	4007 (34.8%))	1082 (38.1%)	726 (39.3%)
Previous lumbar spine surgery	2968 (25.3%)	1025 (35.3%)	703 (37.1%)
MRI central stenosis	8288 (69.8%)	2104 (71.3%)	1372 (71.4%)
MRI lateral stenosis	6796 (57.2%)	1616 (54.8%)	878 (45.7%)
MRI foraminal stenosis	1225 (10.3%)	337 (11.4%)	218 (11.3%)
X ray Degen olisthesis	1854 (15.6%)	416 (14.1%)	281 (14.6%)
Leg pain > 12 months duration	7115 (65.1%)	1940 (72.9%)	1295 (73.8%)
Back pain > 12 months duration	8415 (75.4%)	2267 (82.3%)	1507 (83.7%)
Preoperative ODI **	40.3 (40.1 – 40.6)	48.1 (47.6 – 48.6)	50.8 (50.2 – 51.4)
Preoperative leg pain (NRS) ***	6.59 (6.55 – 6.63)	7.05 (6.97 – 7.12)	7.22 (7.12 – 7.32)
Preoperative back pain (NRS) ***	6.53 (5.49 – 6.57)	7.24 (7.17 – 7.31)	7.44 (7.35 – 7.52)
Preoperative EQ-5D****	0.363 (0.357 – 0.369)	0.253 (0.241 – 0.265)	0.205 (0.191 – 0.219)
Multilevel surgery	4230 (36.0%)	1163 (40.0%)	758 (40.1%)

- * ASA = American Society of Anesthesiologists classification (1-5)
- **ODI = Oswestry Disability Index (0-100), indicating increasing disability
- ***NRS = Numeric Rating Scale (0-10), indicating increasing pain
- ****ED-5D = EuroQol`s quality of life, (-0.60 – 1.00), indicating increasing quality of life

Table 2: Surgical treatment for 11873 Norwegian patients with lumbar spinal stenosis.

	All patients, n=11873 Mean (95%CI), or n (%)	Failure (ODI>31),n= 2950 Mean (95%CI), or n (%)	Worsening (ODI>39), n= 1921 Mean (95%CI), or n (%)
Fusion surgery	1494 (12.6%)	417 (14.1%)	286 (14.9%)
Fusion, TLIF*	429 (3.6%)	105 (3.6%)	73 (3.8%)
Fusion, PLIF**	44 (0.4%)	14 (0.5%)	11 (0.6%)
Fusion, PLF***	1010 (8.5%)	295 (10.0%)	201 (10.5%)
Fusion, other	11 (0.1%)	5 (0.2%)	2 (0.1%)
Decompression			
Unilateral foramenotomy	2705 (22.8%)	642 (21.8%)	401 (20.9%)
Bilateral Foraminotomy	4605 (38.8%)	1057 (35.8%)	699 (36.4%)
Cross over / "over the top"	1932 (16.3%)	462 (15.7%)	307 (16.0%)
Laminectomy	2821 (23.8%)	835 (28.3%)	538 (28.0%)
More than one level operated	4230 (36.0%)	1163 (40.0%)	758 (40.1%)
Microscopic assisted surgery	9577 (80.7%)	2279 (77.3%)	1479 (77.0%)

***Transforaminal Lumbar Interbody Fusion**
****Posterior Lumbar Interbody Fusion**
*****Posterolateral Lumbar Fusion**

Resultater 12 mnd etter operasjon.

ODI	23.9 (23.5 – 24.2)
ODI bedring	15.9 (15.5 – 16.3)

	Failure	Worsening
ODI final score*(missing 44)	2950 (33.2%)	1921 (21.6%)
ODI change **(missing 93)	2893 (32.8%)	2132 (24.2%)
ODI % change***(missing 106)	2849 (32.3%)	2106 (23.9%)

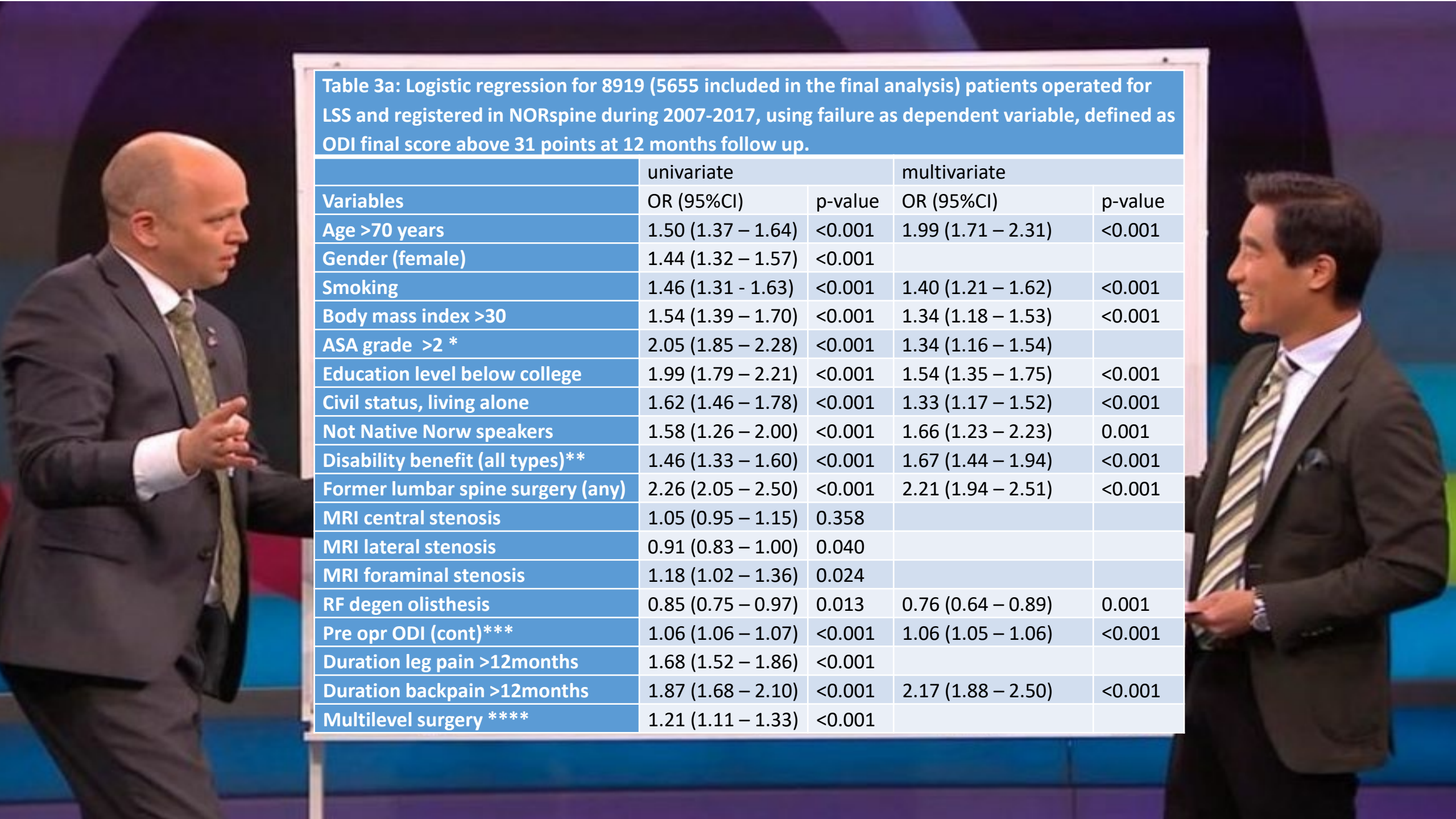


Table 3a: Logistic regression for 8919 (5655 included in the final analysis) patients operated for LSS and registered in NORspine during 2007-2017, using failure as dependent variable, defined as ODI final score above 31 points at 12 months follow up.

	univariate		multivariate	
Variables	OR (95%CI)	p-value	OR (95%CI)	p-value
Age >70 years	1.50 (1.37 – 1.64)	<0.001	1.99 (1.71 – 2.31)	<0.001
Gender (female)	1.44 (1.32 – 1.57)	<0.001		
Smoking	1.46 (1.31 - 1.63)	<0.001	1.40 (1.21 – 1.62)	<0.001
Body mass index >30	1.54 (1.39 – 1.70)	<0.001	1.34 (1.18 – 1.53)	<0.001
ASA grade >2 *	2.05 (1.85 – 2.28)	<0.001	1.34 (1.16 – 1.54)	
Education level below college	1.99 (1.79 – 2.21)	<0.001	1.54 (1.35 – 1.75)	<0.001
Civil status, living alone	1.62 (1.46 – 1.78)	<0.001	1.33 (1.17 – 1.52)	<0.001
Not Native Norw speakers	1.58 (1.26 – 2.00)	<0.001	1.66 (1.23 – 2.23)	0.001
Disability benefit (all types)**	1.46 (1.33 – 1.60)	<0.001	1.67 (1.44 – 1.94)	<0.001
Former lumbar spine surgery (any)	2.26 (2.05 – 2.50)	<0.001	2.21 (1.94 – 2.51)	<0.001
MRI central stenosis	1.05 (0.95 – 1.15)	0.358		
MRI lateral stenosis	0.91 (0.83 – 1.00)	0.040		
MRI foraminal stenosis	1.18 (1.02 – 1.36)	0.024		
RF degen olisthesis	0.85 (0.75 – 0.97)	0.013	0.76 (0.64 – 0.89)	0.001
Pre opr ODI (cont)***	1.06 (1.06 – 1.07)	<0.001	1.06 (1.05 – 1.06)	<0.001
Duration leg pain >12months	1.68 (1.52 – 1.86)	<0.001		
Duration backpain >12months	1.87 (1.68 – 2.10)	<0.001	2.17 (1.88 – 2.50)	<0.001
Multilevel surgery ****	1.21 (1.11 – 1.33)	<0.001		

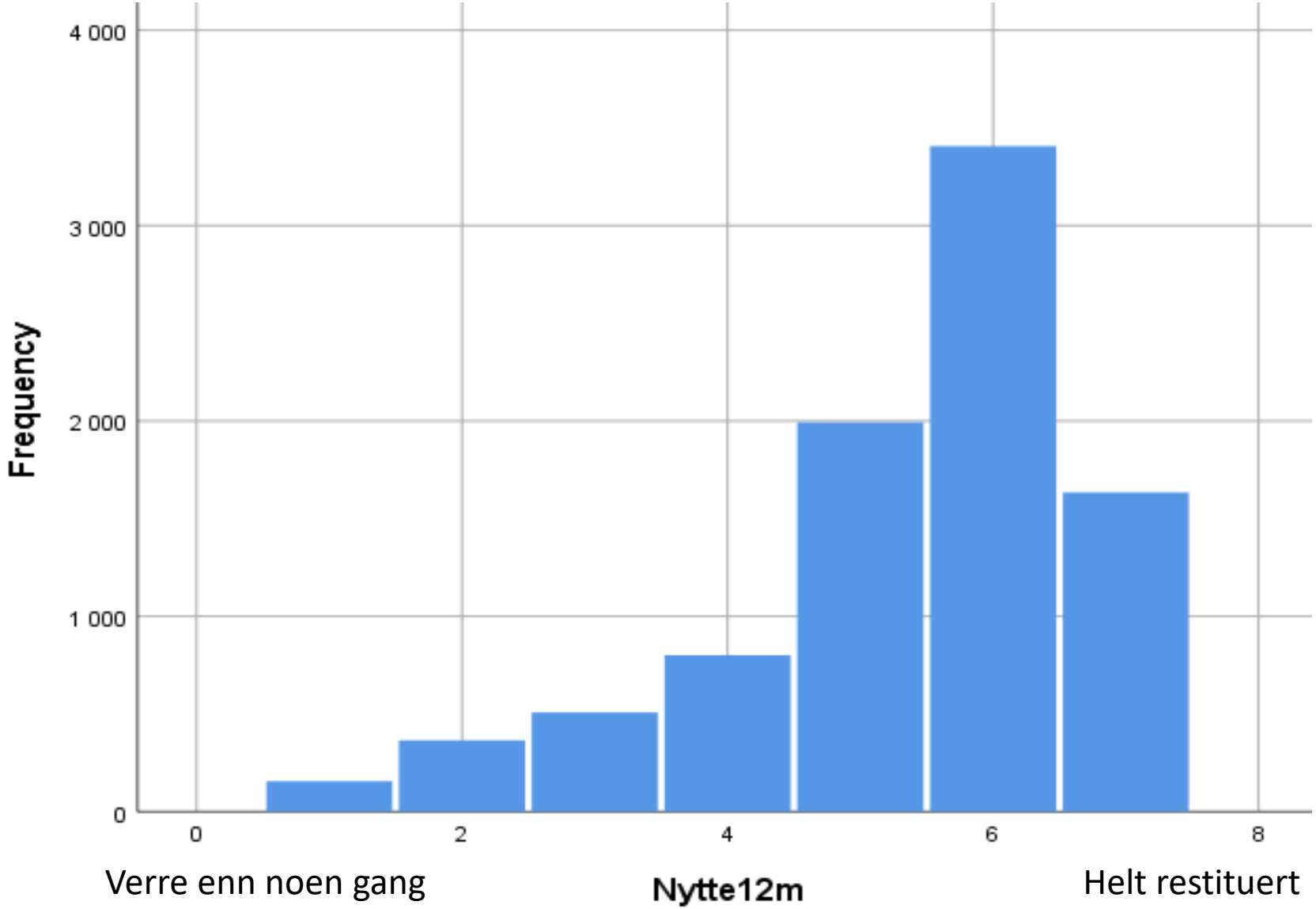
BERG-RUSS 79
Member of: MPEFC (Miss Piggy's elleville fan club)

Jonas Gahr Støre
Russeformann & kermitianer

Det er bedre å være rik og frisk, enn fattig og syk.

Riisbekkveien 6, Oslo 3
Tlf.: 14 13 11

Global Perceived Effect, GPE

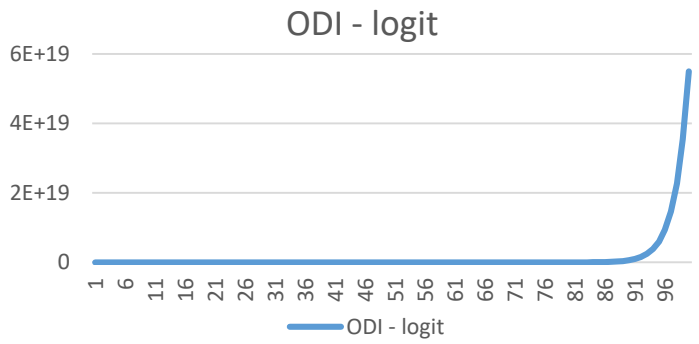


Verre enn noen gang

Helt restituert

Logistisk regresjon

Figure 1
Ikke lineært forhold mellom preopr ODI og logit (OR)



Korrelasjoner mellom kovariater			
		Pearson	spearman
ASA>2	BMI>30		0.085
ASA>2	Tidl sykd (dik)		0.299
ASA>2	Røyk		-0.003
Beinsm>1år	Ryggsm>1år		0.687
Beinsm>1år	NRS beinsm	0.085	0.063
Ryggsm>1år	NRS ryggsm	0.115	0.085
NRS rygg	NRS beinsm	0.600	0.648
NRS ryggsm	ODI	0.534	0.537
NRS beinsm	ODI	0.467	0.476
Single	Har barn		-0.118
Not native norw	Sykepenger		0.066
Not working	Sykepenger		0.301
Lav utdannelse	Røyk		0.115

Interaksjoner

Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	6713,331[a]	,212	,296
2	6713,369[a]	,212	,296
3	6713,414[a]	,212	,296
4	6713,642[a]	,212	,296
5	6713,968[a]	,212	,296
6	6715,976[a]	,212	,296
7	6718,763[a]	,211	,295
8	6722,456[a]	,211	,295
9	6727,402[a]	,210	,294
10	6732,368[a]	,210	,293

a. Estimation terminated at iteration number 5 because parameter estimates changed by less than ,001.

- Ikke alle blir bra etter operasjon for spinal stenose.

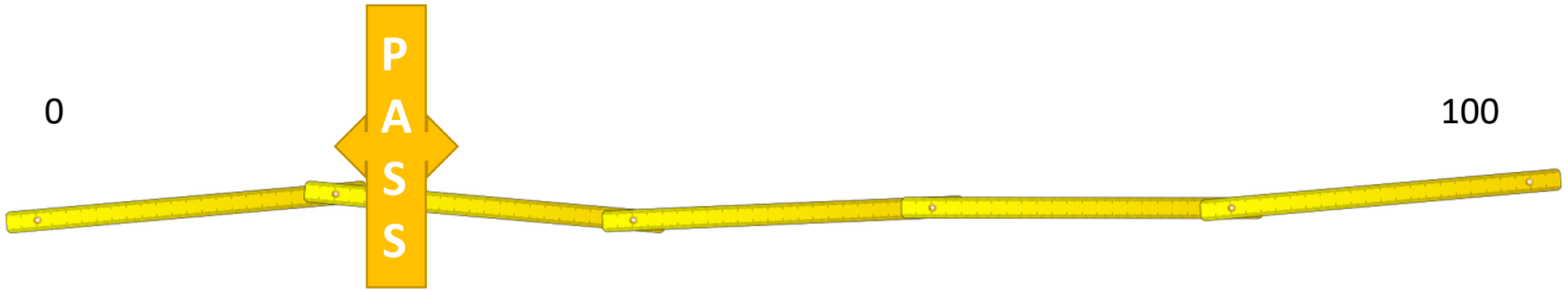
- Sosioøkonomiske baselinefaktorer er viktige (Asher 2017).
  - Etikk, likt tilbud for alle ?

- Datakvalitet. Pasientrapporterte +. Legerapporterte -.
- Variablene NKR målbare, men kanskje «pseudoprediktorer»
- Kirurgiske faktorer mindre viktige
  - Fusjons- og dura-studier underbygger

- 30% failure = 0,4 odds
- OR på 2 gir odds på 0,8 som er lik 4,5/5,5, dvs 45%

- 30% BLIR 45% RISK VED or 2 (ALDER, TIDL OPR, RYGGSM>12MND)

Minimal Detectable Change



Patient Acceptable Symptom State

Minimum Clinical Important Difference (MCID)

Suksess kriterium