



Patient Reported Outcome Measures-Guided Perioperative Care vs Standard Care in Postoperative Recovery: Randomized Controlled trial in Orthopedic Surgery



Manon EBER MSc ¹, Thomas Perrin MD¹, Nathalie Reinbold¹ , Sophie Diemunsch PhD¹, François Bonnomet MD ³ PhD , Julien Pottecher MD PhD ¹,Elliott Bennett-Guerrero MD⁴, Archia Chahard MD, Nicolas Meyer MD PhD², Noll Eric MD PhD¹

Affiliations: 1, Department of Anesthesiology and Intensive Care, Hautepierre Hospital, Strasbourg University Hospital, France 2, Department of Public Health, Strasbourg University Hospital, France 3, Department of Orthopedic & Trauma Surgery, Hautepierre Hospital, Strasbourg University Hospital, France, 4, Department of Anesthesiology, Stony-Brook Medicine, Stony-Brook, New-York, USA

Hypothesis:

- Patient Reported Outcomes Measures (PROMs) are widely used perioperative health status measurements for research and quality improvement.
- We hypothesized that PROMs could also be useful guiding individual perioperative care

Methods:

- We conducted in the Strasbourg University Hospital (France) a randomized controlled trial comparing PROMs-guided perioperative care using the Quality of Recovery-15 (QoR-15) assessed on postoperative day (POD) 1,3,14 and 28 versus standard care.
- The participants were adults (> 18 years) patients of both genders undergoing osteoarticular surgery in the study hospital affiliated with a social society coverage and able to give written informed consent
- The primary endpoint was the change in the modified French Version of the QoR-15 between the preoperative period and POD 35.
- The secondary outcomes included persistent consumption of opioids at 5-weeks postoperatively
- Data were analyzed using Bayesian methods.

Results:

- We included 280 patients in the study from April 2023 to November 2024.
- The main difference in QoR-15 score between the preoperative and POD 35 assessments was 5.5 [2.9 ; 9.2] points higher in the experimental group compared to the control group.
- The probability that this difference is superior than the accepted Minimal Clinically Important Difference for the QoR-15 scale (6.0) was 39.4%.
- There is a 97.4% probability that the relative risk of persistent opioid consumption in the experimental group (12.3%) has a relative risk (RR) < 1 compared to the control group (21.2%).

QoR-15 Patient Survey

Date: __/__/__ Study #: _____

Preoperative ☐ Postoperative ☐

PART A

How have you been feeling in the last 24 hours?

(0 to 10, where: 0 = none of the time [poor] and 10 = all of the time [excellent])

1. Able to breathe easily	None of the time 0 1 2 3 4 5 6 7 8 9 10 All of the time
2. Been able to enjoy food	None of the time 0 1 2 3 4 5 6 7 8 9 10 All of the time
3. Feeling rested	None of the time 0 1 2 3 4 5 6 7 8 9 10 All of the time
4. Have had a good sleep	None of the time 0 1 2 3 4 5 6 7 8 9 10 All of the time
5. Able to look after personal toilet and hygiene unaided	None of the time 0 1 2 3 4 5 6 7 8 9 10 All of the time
6. Able to communicate with family or friends	None of the time 0 1 2 3 4 5 6 7 8 9 10 All of the time
7. Getting support from hospital doctors and nurses	None of the time 0 1 2 3 4 5 6 7 8 9 10 All of the time
8. Able to return to work or usual home activities	None of the time 0 1 2 3 4 5 6 7 8 9 10 All of the time
9. Feeling comfortable and in control	None of the time 0 1 2 3 4 5 6 7 8 9 10 All of the time
10. Having a feeling of general well-being	None of the time 0 1 2 3 4 5 6 7 8 9 10 All of the time

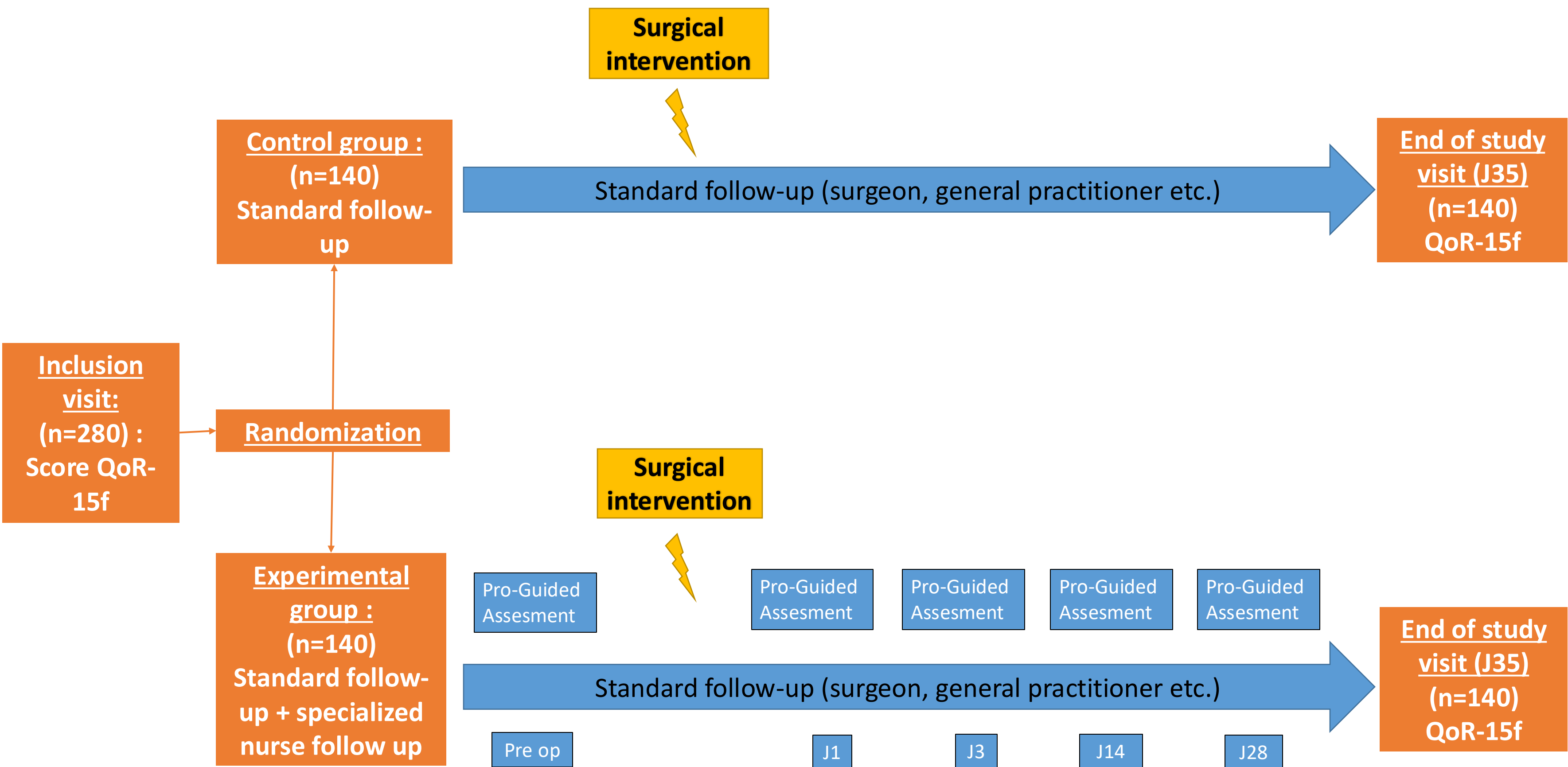
PART B

Have you had any of the following in the last 24 hours?

(10 to 0, where: 10 = none of the time [excellent] and 0 = all of the time [poor])

11. Moderate pain	None of the time 10 9 8 7 6 5 4 3 2 1 0 All of the time
12. Severe pain	None of the time 10 9 8 7 6 5 4 3 2 1 0 All of the time
13. Nausea or vomiting	None of the time 10 9 8 7 6 5 4 3 2 1 0 All of the time
14. Feeling worried or anxious	None of the time 10 9 8 7 6 5 4 3 2 1 0 All of the time
15. Feeling sad or depressed	None of the time 10 9 8 7 6 5 4 3 2 1 0 All of the time

Figure 1 QoR-15 Stark PA, Myles PS, Burke JA, Anesthesiology 2013 ; 118:1332-40



*J35 Evaluation at postoperative day 35 by an external assessor, collecting PROMs and opioid consumption data

Figure 2 : Experimental FlowChart

Criteria	Control group (n=140)	Experimental group (n=139)
Age, year, Mean (SD)	67.4 (11.6)	66.4 (12.1)
Gender (M/F,%)	Male 55.7% / Female 44.3%	Male 46%/Female 54%
ASA:		
I	7.1%	7.9%
II	52.1%	56.8%
III	40.7%	34.5%
IV	0%	0.7%
Type of surgery		
THA	19.3%	20.9%
TKA	22.9%	23%
Revision THA	7.1%	4.3%
Revision TKA	7.1%	5.0%
Shoulder arthroplasty	5.0%	3.6%
Spine surgery	17.1%	20.9%
Other	21.4%	22.3%

Figure 3 : Demographics Results

	Control group (n=140)	Experimental group (n=139)	Difference between groups (95% CI)
Pre op mQoR-15F mean (SD)	114.1 (17.5)	115.0 (17.5)	-
POD 35 mQoR-15f Mean (SD)	112.8 (17.9)	128.3 (13.9)	-
Delta QoR-15 (POD 35 pre op) = primary outcome)	8.1 (5.8 - 10.4)	13.3 (10.5 -16)	5.2 (1.6 - 8.8)
Persistant opioid use			
No	108 (78.8%)	121 (87.7%)	0.59 (0.35 ; 1.00)
Yes	29 (21.2%)	17 (12.3%)	Pr (RR<1) = 0.975
Missing	3	1	
Initial Hospital Lenght of Stay (days)	5.0 (3.0-6.0)	4.0 (3.0-6.0)	0.78 (0.49 ; 1.2)
Missing	3	1	Pr(RR<0) = 0.867
Complications			
No			1.40 (1.19; 1.71)
Yes	1	1.0 (0.0-3.0)	Pr(RR>1)> 0.999
Missing			

Figure 4 Primary and secondary end points

Discussion:

PROMs-guided perioperative care improved the health status however it was less than the prespecified clinically important difference. PROMs guided care significantly decreased the 5-week postoperative persistent opioid consumption