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Recovery after nasal surgery vs. tonsillectomy: discriminant validation of the Postoperative Quality of Recovery Scale

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Background: Initial validation and feasibility of the Post-Operative Quality of Recovery Scale (PQRS) was published in 2010. Ongoing validation includes studies to determine whether this scale can discriminate differences in recovery in similar patients having different surgery.

Methods: A prospective observational study included 89 patients undergoing nasal surgery and 46 patients undergoing tonsillectomy as the primary surgical procedure. Patients were assessed using the PQRS. Assessments were performed pre-surgery, at 15 and 40 min, 1 and 3 days, and 3 months after surgery.

Results: Tonsillectomy patients were younger [25.0 standard deviation (SD) 17.8 vs. 32.1 SD 18.0 years, $P = 0.031$] and had shorter anaesthesia duration (29.5 SD 12.6 vs. 42.7 SD 15.8 min, $P < 0.01$). Tonsillectomy patients had worse recovery in the nociceptive (pain and nausea; $P < 0.001$), activities of daily living

($P < 0.001$) and overall recovery ($P = 0.025$) domains, but were not different in the cognitive, emotive (depression and anxiety) or physiological recovery domains. Complete satisfaction was lower for tonsillectomy ($P < 0.001$). At 3 months, there was equivalence between groups in all assessments.

Conclusion: The study shows the ability of the PQRS to discriminate recovery in different domains. Tonsillectomy has a worse recovery profile over the first 3 days in nociceptive, activities of daily living and overall recovery, which is associated with poorer satisfaction than nasal surgery.

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QUALITY of recovery after surgery and anaesthesia is increasingly being recognised as an important end point to supplement existing end points of mortality, morbidity and length of stay. Importantly, it is a patient-focused outcome. Prior quality of recovery tools have been limited in scope to the immediate hospital period, have a narrow focus, such as physical safety or satisfaction, or rely on subjective recall rather than objective measurement of recovery. Most current research tools are designed to assess short-term recovery and not purposely designed to measure recovery over multiple time periods.^{1–5} In addition, many collapse the different aspects of recovery to produce a composite score, resulting in a statistically convenient but data poor end point.^{2,3,6}

Work attribution: Work is attributed to the Department of Surgery, The University of Melbourne.

The Post-Operative Quality of Recovery Scale (PQRS) is a tool designed to measure quality of recovery after anaesthesia and surgery, and was designed to overcome the limitations of previous scales.⁷ The scale has been demonstrated to show face validity and feasibility, but to be of use, it needs to be able to demonstrate a capacity to discriminate differences in recovery between different patient cohorts and surgical procedures. PQRS measures recovery in five domains [physiological; nociceptive – pain and nausea; emotive – anxiety and depression; activities of daily living (ADL); and cognition]. Recovery is defined as a return to baseline scores (pre-surgery) or better. For the cognitive domain, a tolerance factor is included to account for normal variability in performance on cognitive tests.⁸ The scale is designed for repeated measurements over time and includes parallel forms for cognitive testing to reduce the effect of learning on performance.

The aim of this study is to provide further discriminant validation for the PQRS. Tonsillectomy is known to have a prolonged pain period (7–10 days), requiring considerable multimodal analgesia.^{9,10} Nasal surgery is often performed in similarly aged patients to tonsillectomy, and with similar duration of anaesthesia. However, the pain process is shorter, with multimodal pain relief typically required for 2–3 days.^{11,12} By 3 months, it is reasonable to anticipate no differences in recovery between these two groups. We aimed to measure the recovery profiles of these two cohorts of patients to identify whether the PQRS can discriminate recovery in particular in pain and nausea.

Materials and methods

The study was approved by the University of Melbourne Human Ethics Committee (0718634.1). The University of Melbourne, Parkville 3053, on 5 September 2007, and all patients provided informed written consent. For patients under the age of 18 years, informed written consent was obtained by their parent or legal guardian. This study was conducted at the Northpark Private Hospital in Melbourne, Australia and conducted between 2008 and 2010. Data collection was performed via face-to-face interview during the hospital admission and via telephone interview after hospital discharge by a researcher trained in using the PQRS.⁸ Minors were interviewed in the presence of a parent. The patients were all managed by the same anaesthesiologist and surgeon.

Patients were recruited if they were 6 years or older and having tonsillectomy or a nasal operation as their primary procedure. Nasal surgery included turbinate bone surgery, septoplasty, rhinoplasty or functional endoscopic sinus surgery. In both groups, additional surgery such as adenoidectomy was permitted. However, patients having major nasal surgery in addition to tonsillectomy were excluded. Patients were excluded from recruitment if they were not fluent in English as they may be unable to answer the PQRS questions adequately.

The anaesthesia and analgesia regimen was as follows:

1. Pre-medication for children with oral acetaminophen 10 mg/kg and midazolam 0.1 mg/kg up to a maximum of 5 mg. Pre-medication for adults was 2 Di-gesic tablets (containing total of 650 mg acetaminophen and 65 mg of dextropropoxyphene) and temazepam 20 mg.
2. Induction of anaesthesia was via inhalational sevoflurane in children and in some young adults, or via intravenous propofol in adults. Intraoperative midazolam was not used. Maintenance of anaesthesia was with desflurane titrated to need in 100% oxygen. Nitrous oxide was not used in any cases. The airway was maintained using a flexible laryngeal mask airway.
3. Intraoperative analgesia was morphine 0.1 mg/kg intravenous (i.v.) following insertion of the i.v. cannula.
4. Local anaesthesia infiltration consisted of 2 mg/kg of ropivacaine into the tonsil bed after excision, and for nasal surgery, 4–8 ml of bupivacaine 0.5% with epinephrine 1 : 200,000 was infiltrated. Cocaine 5% nasal packs were inserted after anaesthesia and removed prior to incision.
5. All patients received intraoperative granisetron 15 µg/kg up to 1 mg i.v. and dexamethasone 0.1 mg/kg up to 4 mg i.v. After surgery antiemetics were administered as required. First-line anti-emetic was granisetron 15 µg/kg up to 1 mg i.v. every 12 h, followed by prochlorperazine 12.5 mg intramuscular (i.m.) every 6 h in adults.
6. Post-operative analgesia for nasal surgery consisted of regular oral acetaminophen 10 mg/kg up to 1 g every 6 h, and oral oxycodone 10 mg every 6 h (in adults), and tramadol drops 1.25 mg/kg every 6 h. Ibuprofen suspension 10 mg/kg (or 400 mg as tablets) or subcutaneous morphine 0.1 mg/kg up to 10 mg was used for breakthrough pain.

For tonsillectomy, a strict pain regimen was used, consisting of oral acetaminophen 10 mg/kg up to 1 g, ibuprofen 10 mg/kg (for adults diclofenac 25 mg) every 6 h was alternated with oral oxycodone 10 mg (in adults) or tramadol drops in children 1.25 mg/kg every 6 h. While in hospital patients over 15 years of age received a patient-controlled analgesia device with morphine 1 mg bolus and no background infusion. In children, subcutaneous morphine 0.1 mg/kg up to 10 mg was used for breakthrough pain. Patients were informed that they would require the strict protocol for 7–10 days.

Tonsillectomy was performed using monopolar diathermy, with exposure facilitated with the Boyle Davis gag and Draffin rings for neck extension. Nasal surgery was performed using instruments and monopolar diathermy. Nasal packing was not performed, but rather Doyle silastic nasal splints were used instead.

Outcomes

The primary outcome was the quality of recovery in each domain of the PQRS over the 3-month follow-up period. Secondary outcomes included analysis of the overall perspective domain of the PQRS, which includes patients' satisfaction with surgery and anaesthesia.

Assessment protocol

Patients were recruited on the same day as surgery, and baseline measurements using the PQRS were performed prior to surgery. The PQRS was repeated at 15 min, 40 min, 1 day, 3 days and 3 months following surgery using the same testing paradigm used in the feasibility and face validation study.⁷

Potential sources of bias

We reduced the risk of different anaesthetic and surgical techniques by restricting participants to one anaesthesiologist and one surgeon. The techniques including drug use and post-operative pain relief were not changed during this period. We examined the 'real-world' situation where there are both children and adults presenting for tonsillectomy and nasal surgery, and the PQRS has previously been shown to be feasible in younger patients.⁷ As a result, the pragmatic study included a wide range of ages, but no further analysis was performed on age, as the numbers in each age band were too small. The overarching aim of the study was to show discriminant validation rather than to investigate the cause of differences in the recovery profiles.

Study size

Recruitment was by convenience sampling leading to a difference in group numbers. Sample-size estimates were based on the PQRS feasibility and face validation study⁷ where estimates were based on modelling using Cochrane–Mantel–Haenzel approach for repeated measurements of proportions and an anticipated greatest difference on day 1. As we anticipated a large difference in recovery between groups for certain domains (such as nociception), a minimal sample of 45 patients in each group would allow discrimination of an odds ratio of 5, with alpha of 0.05 and power of 0.8.

Statistical methods

Group recovery is expressed as the proportion of patients recovered at each time point. The definition of recovery was return to baseline values or better.⁷ For the cognitive domain, a tolerance factor is intro-

duced to allow for normal performance variability.⁸ This means, that patients are allowed to be 'a little worse' than baseline and still score as recovered. Specifically, recovery is defined for each question in the cognitive domain according to the change scores (post-operative value minus baseline value): orientation ≥ 0 , digits forward ≥ -2 , digits back ≥ -1 , word recall ≥ -3 and word generation ≥ -3 . Patients whose baseline scores in the cognitive domain were less than or equal to the tolerance factor were excluded from the cognitive and all-domains analysis as they would automatically to be scored as recovered. The analysis technique for recovery parameters was the Cochrane–Mantel–Haenzel test to identify difference between treatment groups over time for repeated measurement of proportions. It is a global test looking at group difference over the whole time period and as such does not require further statistical correction for sampling at multiple time periods.

Results

Eighty-nine patients were enrolled into the nasal surgery group and 46 enrolled for tonsillectomy. Low baseline scores were recorded for at least one question in the cognitive domain in 23 nasal surgery and 13 tonsillectomy patients. These patients were excluded from the cognitive domain and all-domains analysis but were included for other recovery domains. In keeping with the PQRS human volunteer cognitive validation study,⁸ a group recovery exceeding 80% in the cognitive domain is considered to represent 'good recovery' for the group.

The demographic data for the two cohorts is shown in Table 1. Tonsillectomy patients were younger ($P = 0.031$), and anaesthesia duration was shorter ($P < 0.01$), but otherwise were similar. The odds ratio (nasal : tonsillectomy) was calculated for Day 1 to check sample size estimates. For domains with an expected large difference, the odds ratios

Table 1

Patient and operative data.			
Variable, median [interquartile range]	Nasal (n = 89)	Tonsillectomy (n = 46)	P
Age years	24 [31.0]	12.5 [26.8]	0.031
Years of education	12 [6.0]	8.5 [7.5]	0.078
Weight kg	69 [31.0]	46 [47.8]	0.283
Height (cm)	165 [21.0]	148 [41.0]	0.099
Units alcohol/week	0 [2.0]	0 [0.8]	0.489
Anaesthetic duration (min)	35 [21.0]	22.5 [11.0]	< 0.01
Gender – male	51%	47%	0.717
No. patients excluded from cognitive analysis	23	13	

were 6.8 for nociceptive domain, 5.3 for all domains, for ADL (less anticipated difference) was 3.3, and for domains where as difference was not expected were 1.8 for emotive domain and 0.9 for the cognitive domain.

The recovery profiles for the recovery domains are shown in Fig. 1. Tonsillectomy patients had a worse recovery profile in the nociceptive ($P < 0.001$), ADL ($P < 0.001$) and in overall recovery (recovery in all of the domains, $P = 0.025$). There was no differ-

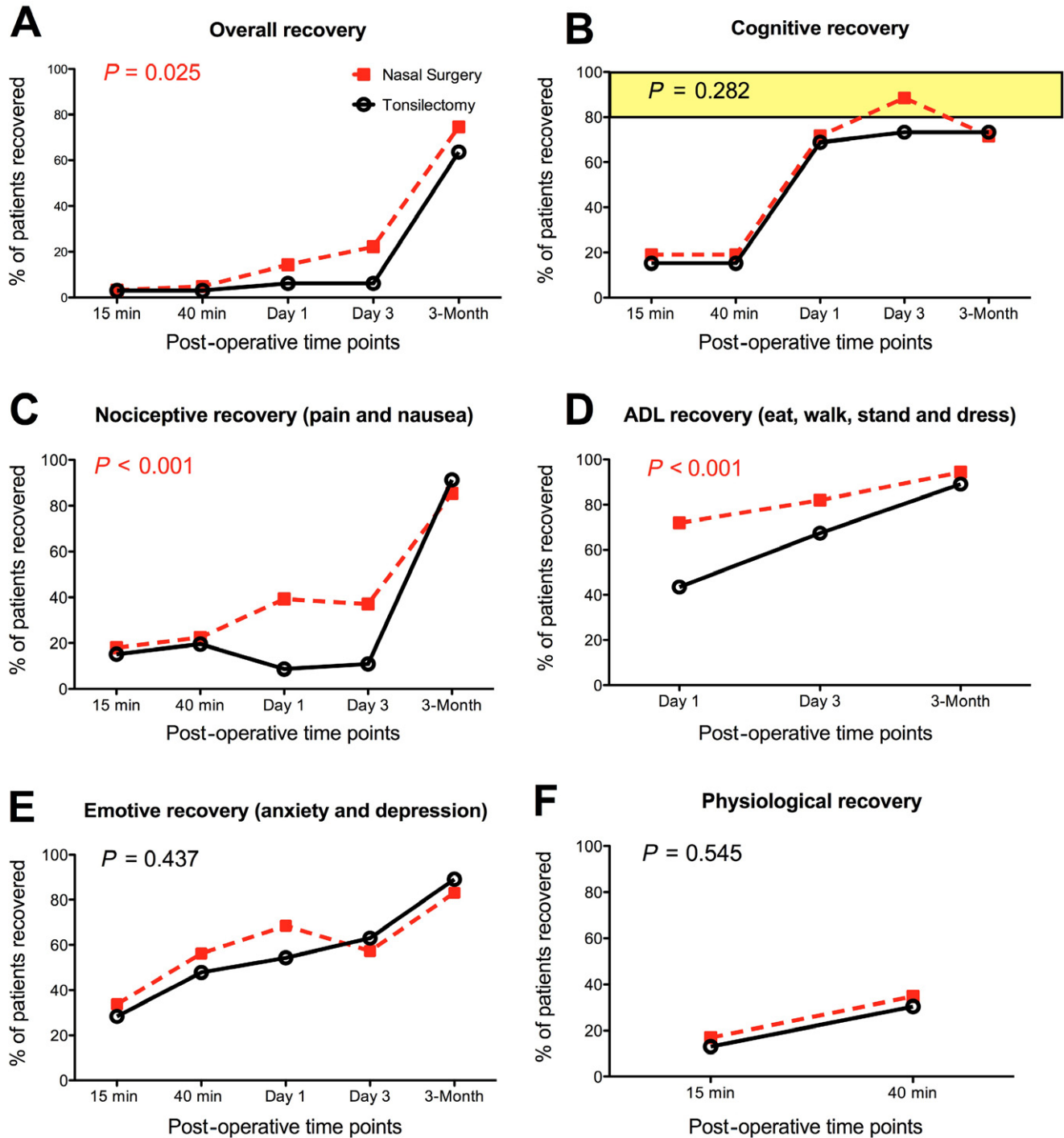


Fig. 1. Recovery profile for nasal surgery and tonsillectomy patients. Times are 15 and 40 min, 1 and 3 days, and 3 months after surgery. The P value is calculated using the Chochran–Mantel–Haenzel test, which tests for difference between groups over time. For cognitive recovery (B), the yellow-shaded region denotes a range of good recovery. ADL, activities of daily living.

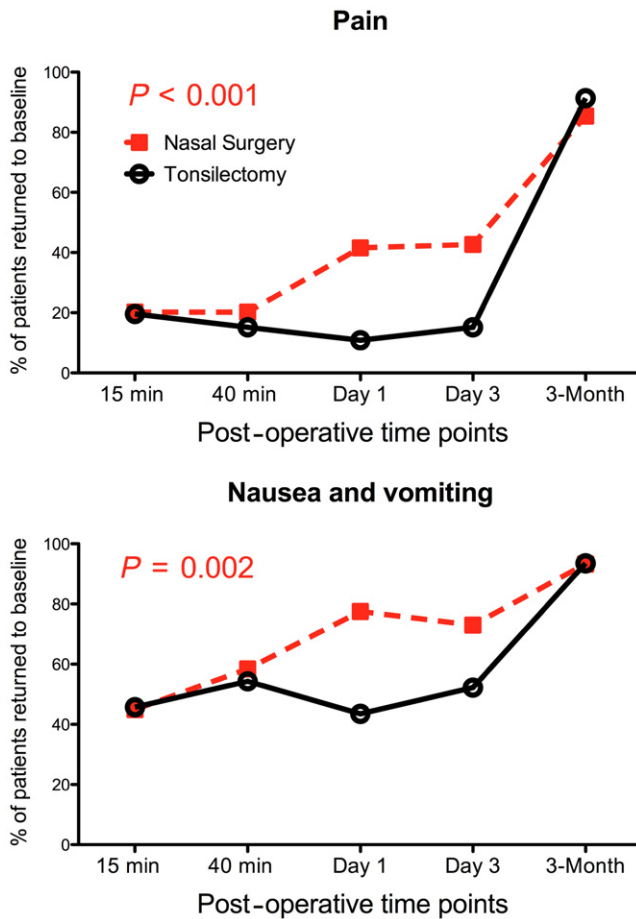


Fig. 2. Recovery profile for nasal surgery and tonsillectomy patients for the pain and nausea questions of the nociceptive domain of the Post-Operative Quality of Recovery Scale. Times are 15 and 40 min, 1 and 3 days, and 3 months after surgery. The P value is calculated using the Cochran–Mantel–Haenszel test, which tests for difference between groups over time.

ence in physiological, emotive (anxiety and depression) or cognitive recovery. At 3 months after surgery, recovery was equivalent between groups.

The nociceptive domain showing separate recovery for pain and nausea is shown in Fig. 2. Tonsillectomy patients had worse recovery than nasal surgery for both pain ($P < 0.001$) and nausea ($P = 0.002$) but were equivalent at 3 months.

The patient perspective domain is a subjective assessment by the patient on the impact of surgery on their ability to perform ADL, clarity of thought, satisfaction and ability to work, and is conducted from day 1 onwards. The impact of surgery is shown in Fig. 3. For tonsillectomy patients, surgery and anaesthesia had a greater impact on clarity of thought ($P = 0.014$) but not for impact on return to work or ADL. Complete satisfaction was very high

for nasal surgery but significantly lower for tonsillectomy ($P < 0.001$).

Discussion

Our study shows that there are large differences in pain and nausea between tonsillectomy and nasal surgery patients, most prominent at the days 1 and 3 time points but not different at 3 months. This is an expected finding^{9–15} and adds to the capacity of the PQRS to discriminate between surgical procedures. We also found an effect on ADL and in overall recovery, which would be consistent with the differences between groups in pain and nausea. We did not expect differences in cognitive recovery, and this was confirmed in this study. We also did not have any expectation on emotive recovery and did not find any differences in this domain. The PQRS was able to discriminate recovery in these groups where expected, even with relatively small sample size.

Patient satisfaction with surgery is typically very high^{16–18} and is a poor discriminator of quality of recovery.¹⁹ We have previously shown that the most important contributor to poor satisfaction is persistent pain or nausea.¹⁹ This is in keeping with our findings in this study where we found significantly lower levels of satisfaction for tonsillectomy patients, especially on days 1 and 3 when pain is high and nausea common.

New measurement scales are typically validated using a large cohort of patients to ensure feasibility, face validity and if there are different cohorts within the study population, the ability to discriminate between groups.^{6,7,20} However, the use of a single study reduces the ability to generalise the validation to other cohorts. We have approached validation as a series of studies, which investigate different procedures on the performance of the domains of the scale. For the PQRS, we have performed feasibility and face validity,⁷ validated (and altered) the cognitive scoring with a human volunteer study,⁸ investigated aspects as satisfaction,¹⁹ and have conducted studies to address discriminant validation. This study identified the expected differences between two similarly aged cohorts undergoing relatively brief surgery to the head region but with well-known differences in pain recovery over the first week after surgery.

The study was designed to identify whether the tool can discriminate between recovery where expected. Where differences were large, the tool was able to discriminate that difference within the estimated sample size, such as for nociception and all

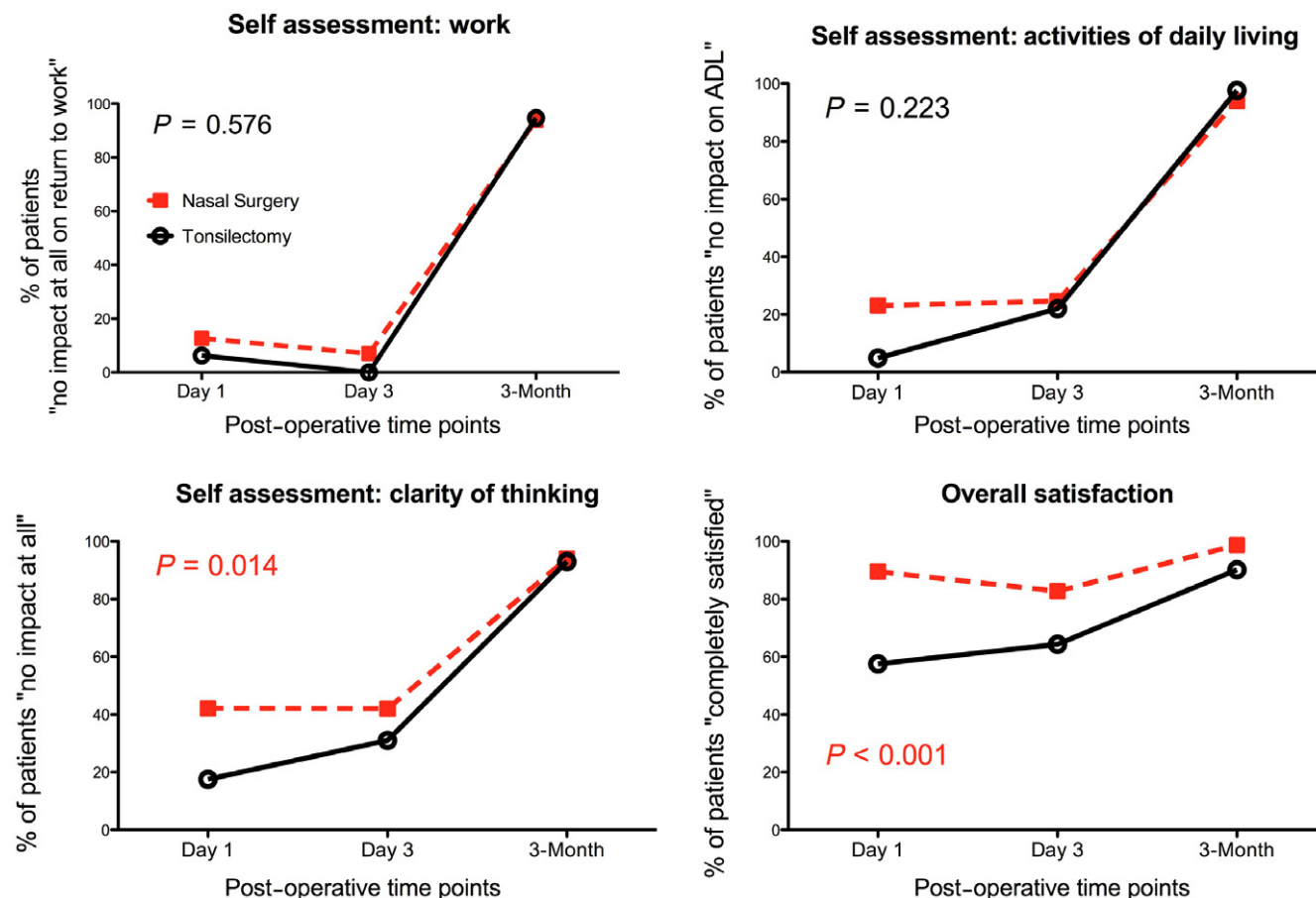


Fig. 3. Subjective patient assessment of the impact of surgery on the ability to perform activities of daily living (ADL), their clarity of thought and satisfaction. For work (top left panel), the proportion of patients who reported that surgery had no impact on their ability to return to work is shown. For ADL (top right panel), the proportion of patients who reported that surgery had no impact on their ability to perform ADL is shown. For clarity of thinking (bottom left panel), the proportion of patients reporting no impact at all. For satisfaction (bottom right panel), those reporting completely satisfied. Times 1 and 3 days, and 3 months after surgery. The P value is calculated using the Cochran–Mantel–Haenszel test, which tests for difference between groups over time.

domains recovery. The sample size was larger than the minimal sample size calculated, which allowed discrimination of smaller differences such as the ADL domain. Where differences were not expected, this was also shown with the PQRS (such as cognition and emotive domains). The tool is suitable for quantitative analysis of differences using the methods outlined in this report, although it is important to ensure adequate sample size for the domains being assessed.

The study was not designed to identify why differences in recovery occur but rather to show discriminant ability. Further studies would be required to look at effects of different aged cohorts or effects of different nasal operation techniques, and we are unable from this dataset to comment on cause of poor recovery. The PQRS, however, may be useful in

the early detection of patients, who may be 'poor recoverers' from the remainder of the cohort who may recover normally, allowing targeted post-operative interventions. In this study, recovery was low in most domains in the first 3 days, which is expected due to the pain and requirement for analgesia. However, cognitive recovery plateaus at day 1, and those patients who have not recovered at day 1 may have delayed cognitive recovery. This has important implications for driving vehicles, returning to work or making life decisions.

There are several limitations to the study. It is an observational study with convenience sampling and has the risk of inclusion bias and operator bias. We have reduced the risk of this bias by using a single anaesthetist and surgeon, and operations performed at a single hospital. The recovery profiles reflect the

particular operations and the surgical and anaesthetic technique, and therefore are not generalisable to all throat or nasal operations. We were primarily interested in the discriminant ability of the PQRS rather than reporting recovery profiles for these operations. The exclusion of patients from the cognitive domain because of low baseline scores is important to reduce a potential ceiling effect, as patients with low baseline scores are less likely to deteriorate further than a patient with high baseline scores. In part, the lack of familiarity with the testing and potential anxiety associated with the forthcoming surgery could reduce performance on these tests. As part of the development of the PQRS, there is now a web delivered survey tool with real-time data entry.* The tool has embedded instructions to read to the patient and a consistent response time allowed for survey questions. This may reduce the potential for rushing through questions and may improve the consistency of the conduct of the scale.

Conclusion

The study shows the ability of the PQRS to discriminate recovery in different domains. Tonsillectomy has a worse recovery profile over the first 3 days in nociceptive, ADL and overall recovery, which is associated with poorer satisfaction than nasal surgery.

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*<http://www.pqronline.org> (accessed on 9 January 2014).