

Only 39% of RCT comparing minimal invasive surgery to conventional surgery for rectal cancer measured “patient-reported outcomes”

Background

High-quality surgical procedures should be based on good surgical outcomes and, ideally, the outcomes should be assessed together with patients' involvement. Rectal surgery is associated with high morbidity including sexual, urinary, and bowel dysfunction. Laparoscopic surgery is considered less invasive than open surgery and has the potential to preserve urogenital function and quality of life. Currently, several less-invasive approaches have been in practical use. However, it is still unclear how much attention was paid to patient-reported outcomes (PROs) in conducting randomized controlled trials (RCTs) of rectal cancer surgery and in incorporating such outcomes into meta-analyses (MAs).

Objective

To clarify how many RCTs and MAs paid attention to PROs for incorporating patients' preferences into studies or reviews.

Methods

This was a cross-sectional analysis. We comprehensively searched MEDLINE and Cochrane Library for the topics including rectal cancer and laparoscopic surgery. Rectal cancer patients, who underwent laparoscopic surgery and other procedures including open, robotic, and transanal surgery, were appropriate for inclusion. We included randomized controlled trials and meta-analyses comparing laparoscopic surgery with other procedures.

Patients' inclusion

Since complications of rectal cancer surgery are frequent and affect the postoperative lives of cancer survivors, shared decision-making considering evidence on PROs is needed, as well as on the assessment of safety and oncological outcomes.

Relevance to patients and consumers

The more patient-reported outcomes are incorporated in researches of rectal cancer surgery, the more researches may reflect patients' values. This analysis investigated the current status of clinical trials, systematic reviews, and meta-analyses of rectal cancer surgery that focused on patient-reported outcomes. The findings of the analysis suggest future tasks of this field to incorporate patients' values more.

Relevance to diversity

Treatment of rectal cancer should be selected based on the values of patients as well as the safety of surgery and oncological prognosis. The values and characteristics of the patient vary, and the evidence for patients and personnel to choose treatment should be built with patients' involvement as much as possible. This analysis focused on the surgical treatment of rectal cancer and patient-reported outcomes. As Cochrane provides the evidence for all, patients' involvement with researches should be encouraged and the researchers on systematic reviews should focus on patient-reported outcomes.

Study ID	Setting	Participants	Subject	Intervention	Comparison	Used PROs
CLASICC	Multicenter	794	Colorectal	Laparoscopic	Open	QLQ-CR38, FSFI, IPSS, IIEF
COLOR II	Multicenter	1103	Rectal	Laparoscopic	Open	EQ-5D, QLQ-C30, QLQ-CR38
COREAN	Multicenter	340	Rectal	Laparoscopic	Open	QLQ-C30, QLQ-CR38
ALaCaRT	Multicenter	475	Rectal	Laparoscopic	Open	QLQ-CR29, QLQ-PR25, AQoL-8D, FSFI, IPSS, IIEF (not reported yet)
ACOSOG Z6051	Multicenter	486	Rectal	Laparoscopic	Open	QLQ-C30, QLQ-CR38, SQOLS, MBFQ, LASA (not reported yet)
ROLARR	Multicenter	471	Rectal	Robotic	Laparoscopic	IPSS, IIEF, FSFI
Tolstrup 2018	Single-center	51	Rectal	Robotic	Laparoscopic	Numerical rating scale (NRS) on pain
Kim 2018	Single-center	163	Rectal	Robotic	Laparoscopic	QLQ-C30
Pontallier 2016	Single-center	100	Rectal	Transanal	Laparoscopic	IIEF, Wexner score, IPSS
Quah 2002	Single-center	236	Rectal	Laparoscopic	Open	IPSS
Wang 2017	Single-center	336	Rectal	Robotic	Laparoscopic	IPSS, IIEF
Wei 2017	Single-center	406	Rectal	Robotic	Laparoscopic	IPSS, IIEF, FSFI
King 2008	Single-center	60	Colorectal	Laparoscopic	Open	QLQ-C30, QLQ-CR38, study-specific questionnaire
Levic 2013	Single-center	40	Rectal	Single-port Lap	Multi-port Lap	Visual analog scale (VAS) on pain

Table 1. Studies which use patient-reported outcomes.

†Abbreviations: Lap, laparoscopic; IPSS, International Prostatic Symptom Score; FSFI, Female Sexual Function Index; IIEF, International Index of Erectile Function; MBFQ, Mayo Bowel Function Questionnaire; LASA, Linear Analog Scale Assessment; SQOLS, Stoma Quality of Life Scales.

Fig 1. Proportions of randomized studies which use PROs

Studies using PROs Studies not using PROs

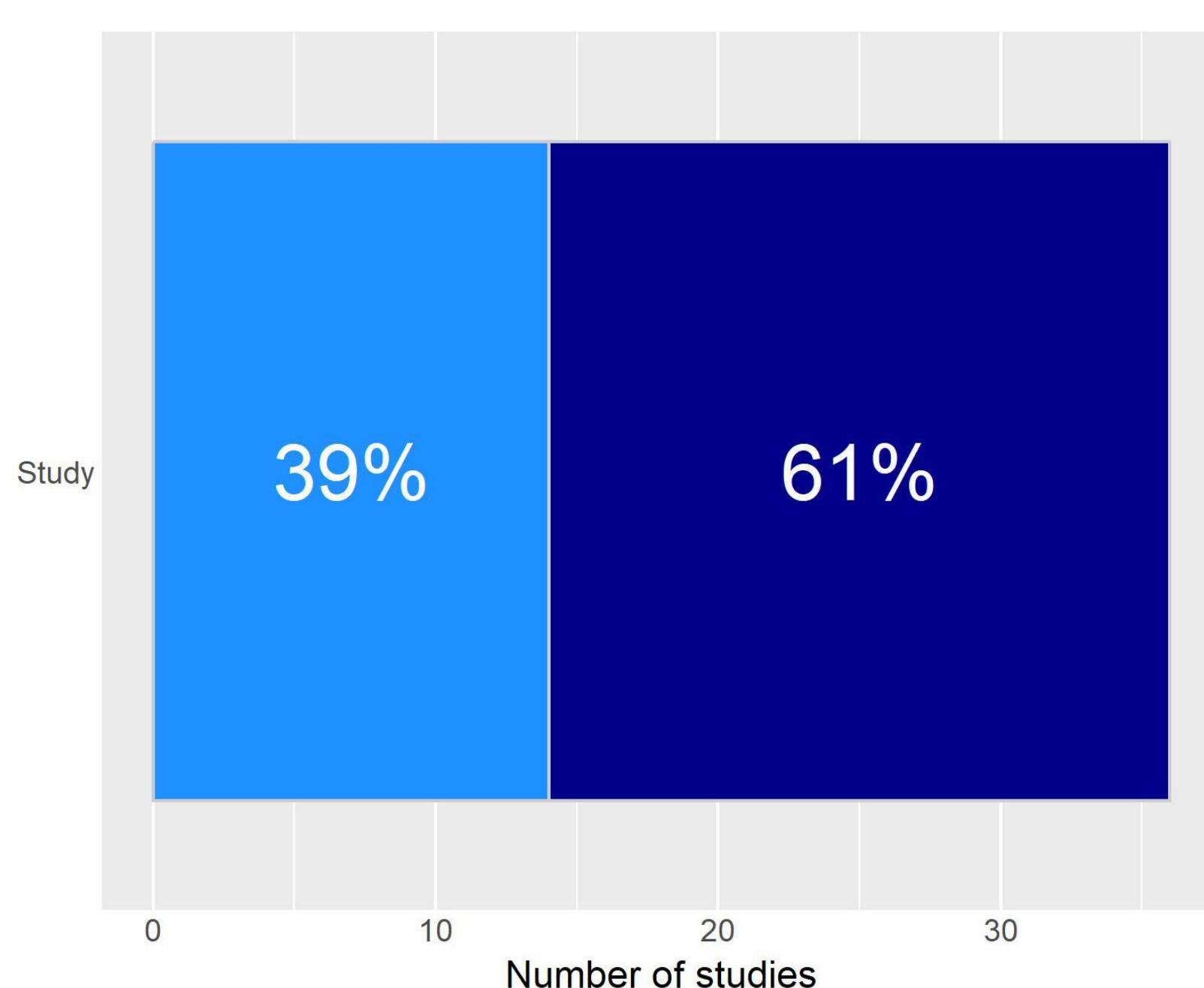


Fig 2. Proportions of meta-analyses which report PROs

Reviews reporting PROs Reviews not reporting PROs

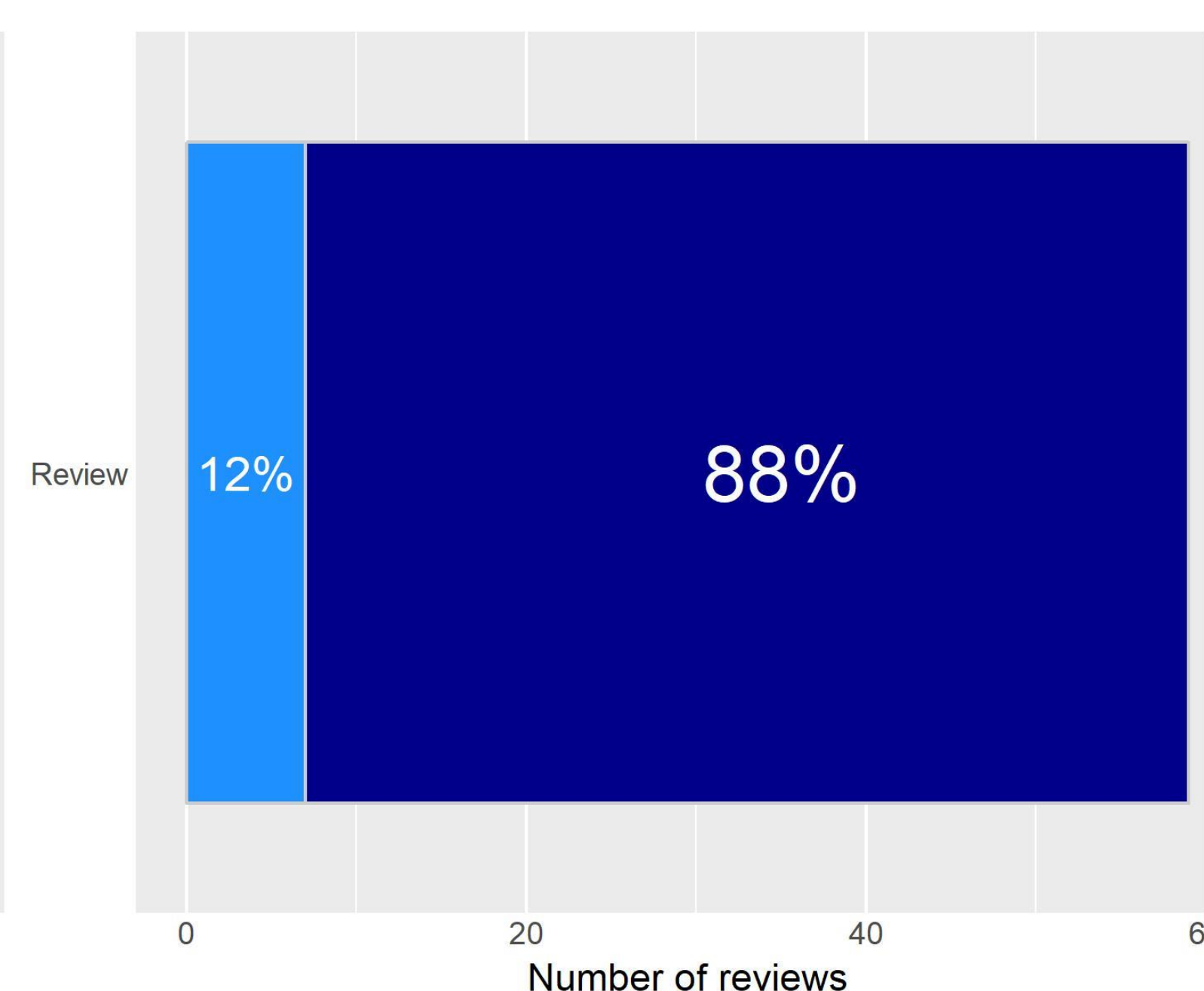


Fig 3. Large studies tend to measure PROs

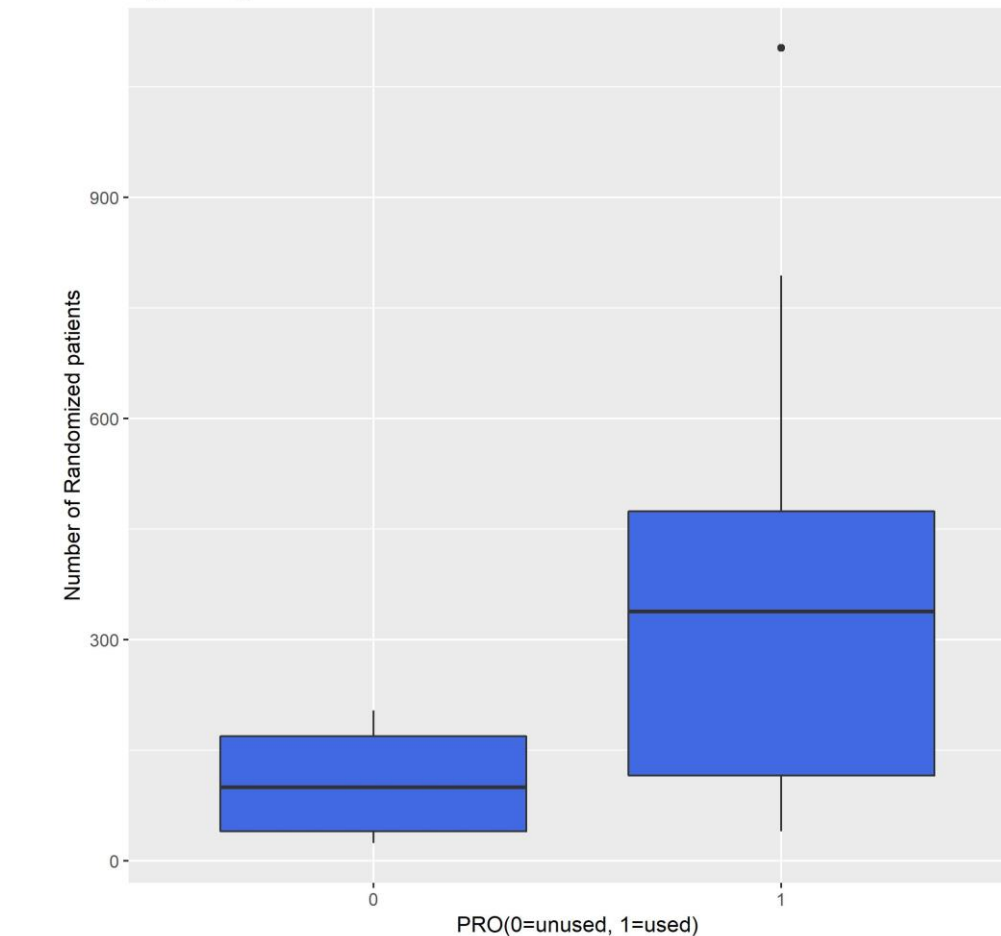
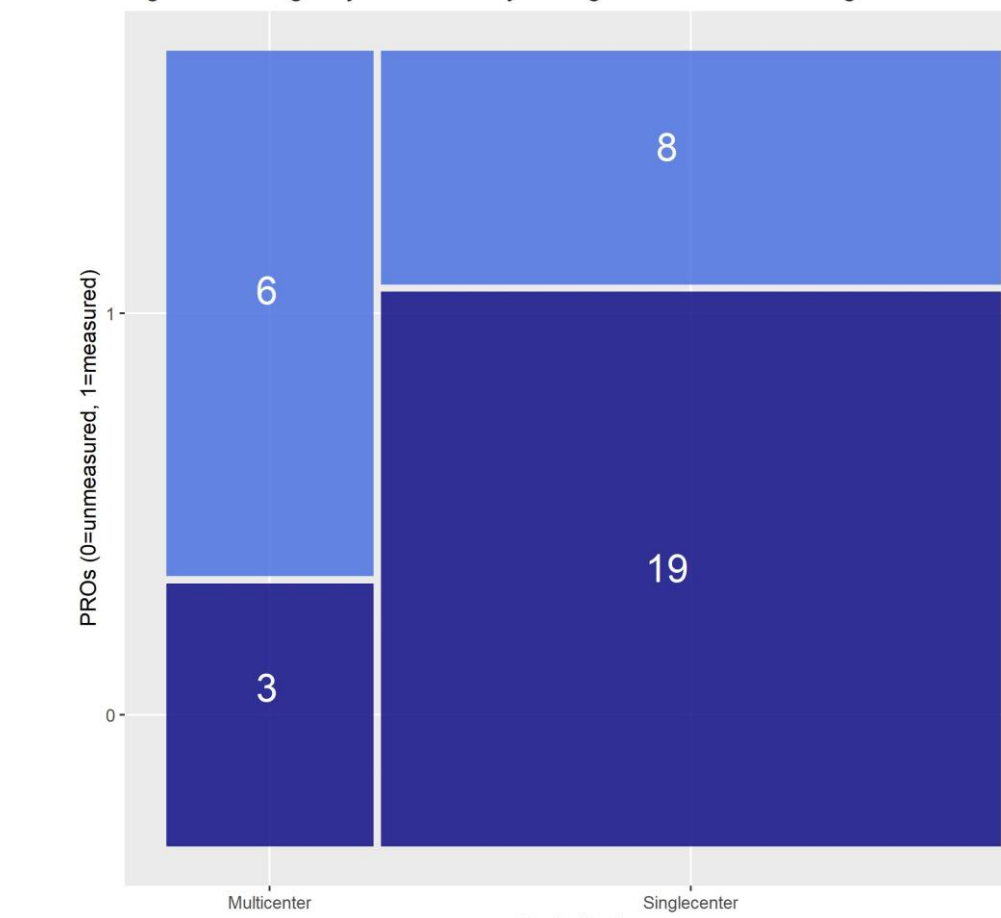


Fig 4. A contingency table of study settings and PRO measuring



Results & Discussions

- Only 14/36 (39%) studies measured PROs, 6 of which were multicenter studies. The remaining 22 studies assessed surgical and oncological outcomes without PROs.
- Large studies with many participants tend to measure PROs.
- As for meta-analyses, only 7/59 (12%) reviews including one Cochrane review set PROs as their outcome.
- Pain scales and urogenital function scores were integrated into the meta-analyses, but QoLs were not.
- As well as surgical and oncological outcomes, evaluation of PROs should be encouraged to build evidence reflecting patients' viewpoints.
- Integrability of QoL should be discussed.

Conclusion

The findings suggest a need for encouraged use for PROs. Incorporating PROs into study outcomes may allow patients' perspective to be reflected in research. Although a time lag might be present before measured PROs are reported, future MAs should incorporate PROs.



How much attention was paid to patient-reported outcomes in randomised trials and meta-analyses of rectal cancer surgery?

Daisuke Nishizaki, Atsuhiko Sumii, Koya Hida, Yoshiharu Sakai
Department of Surgery, Kyoto University, Japan



京都大学
KYOTO UNIVERSITY

#30666

Twitter: @zacksurg, Email: ndaisuke@kuhp.kyoto-u.ac.jp