

Digital Approach to Informed Consent in Bariatric Surgery: A Randomized Controlled Trial

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INTRODUCTION:

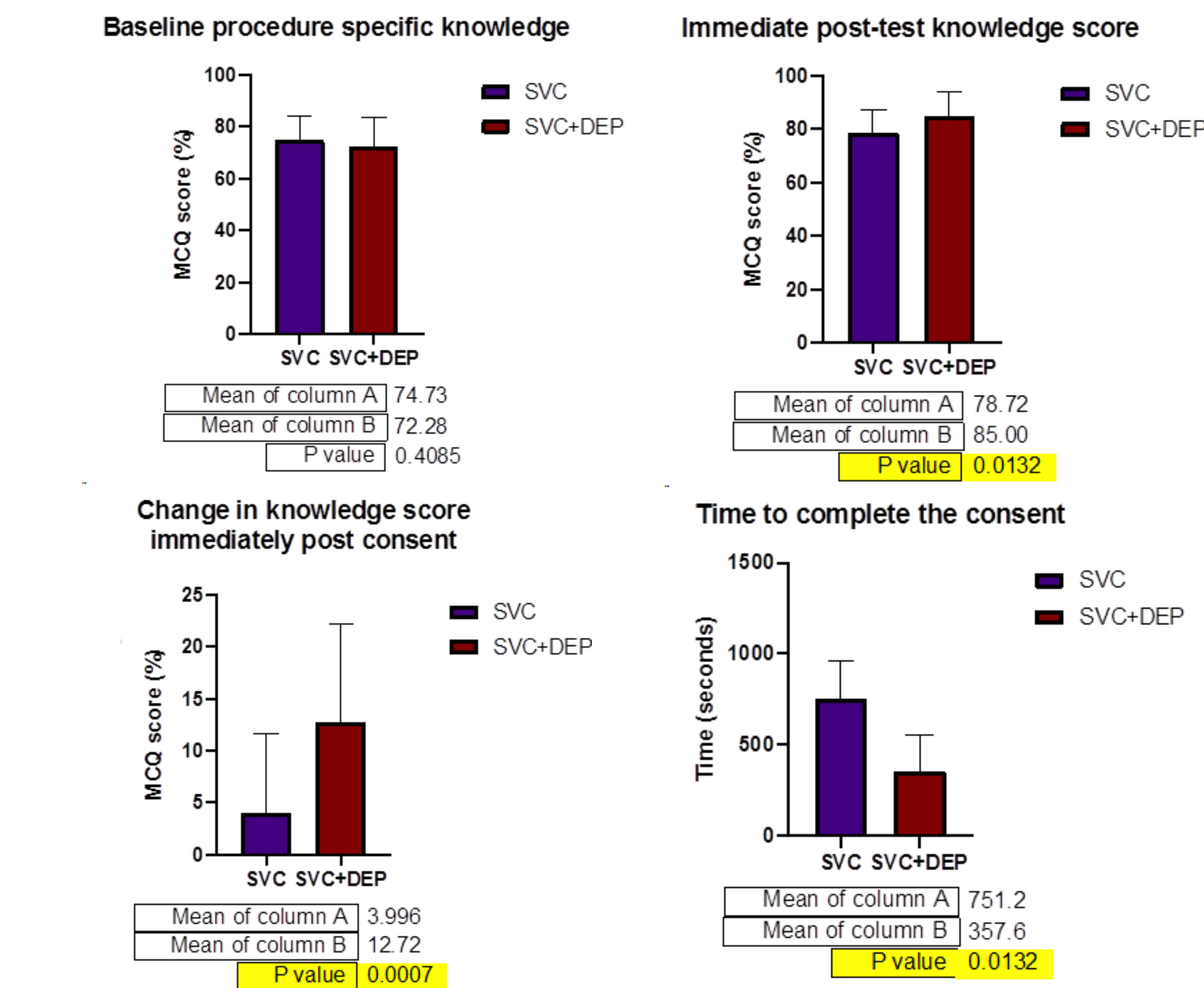
Informed consent is of utmost importance in surgery. Literature suggests that over 20% of consent encounters have no documentation of discussed risks. The purpose of this study was to investigate whether addition of a digital education platform (DEP) to a standard verbal consent (SVC) for patients undergoing laparoscopic Roux-en-Y gastric bypass (LRYGB) results in:

- improved acquisition and retention of procedure-specific knowledge
- equivalent satisfaction with the clinical encounter
- shorter face-to-face time between surgeon and patient to obtain informed consent when compared to SVC alone

METHODS:

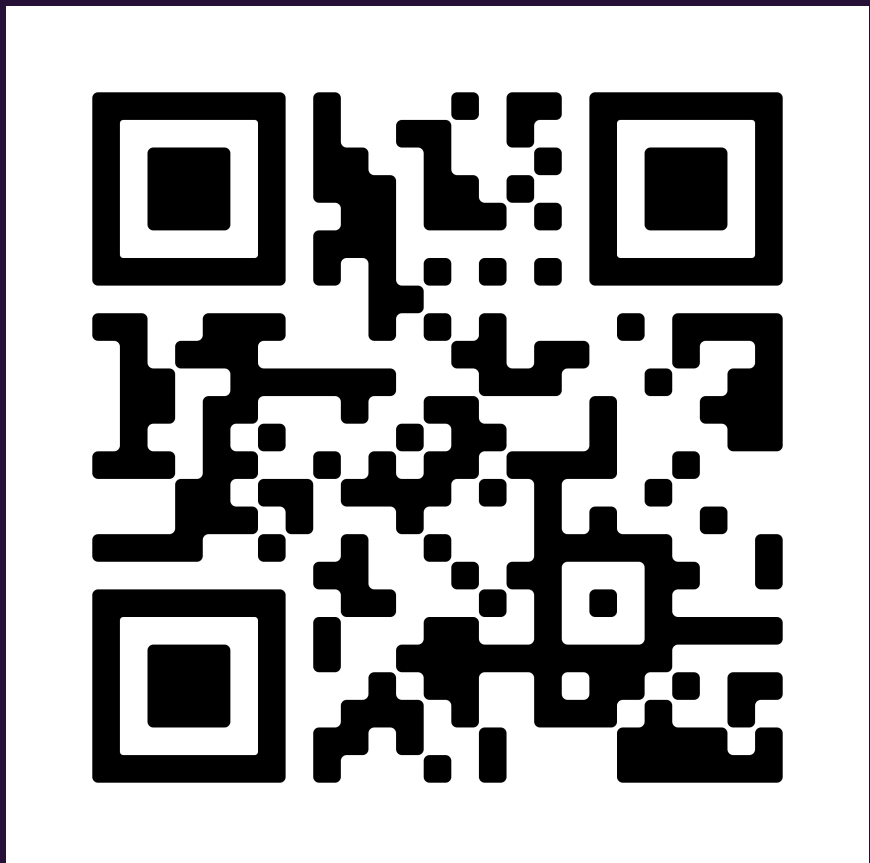
We conducted a prospective randomized controlled trial at a tertiary care academic hospital. Patients were randomized to an intervention arm (DEP+SVC) or a control arm (SVC). DEP was an interactive, video-supplemented online module that discussed risks, benefits, expectation, and outcomes for a LRYGB. Study outcomes included patients’ immediate and delayed (6-weeks) retention of procedure-specific knowledge (multiple choice test), satisfaction with the clinical encounter (Client Satisfaction Questionnaire, CSQ-8), and the duration of time required for a face-to-face interaction between a surgeon and a patient to obtain an informed consent.

RESULTS:

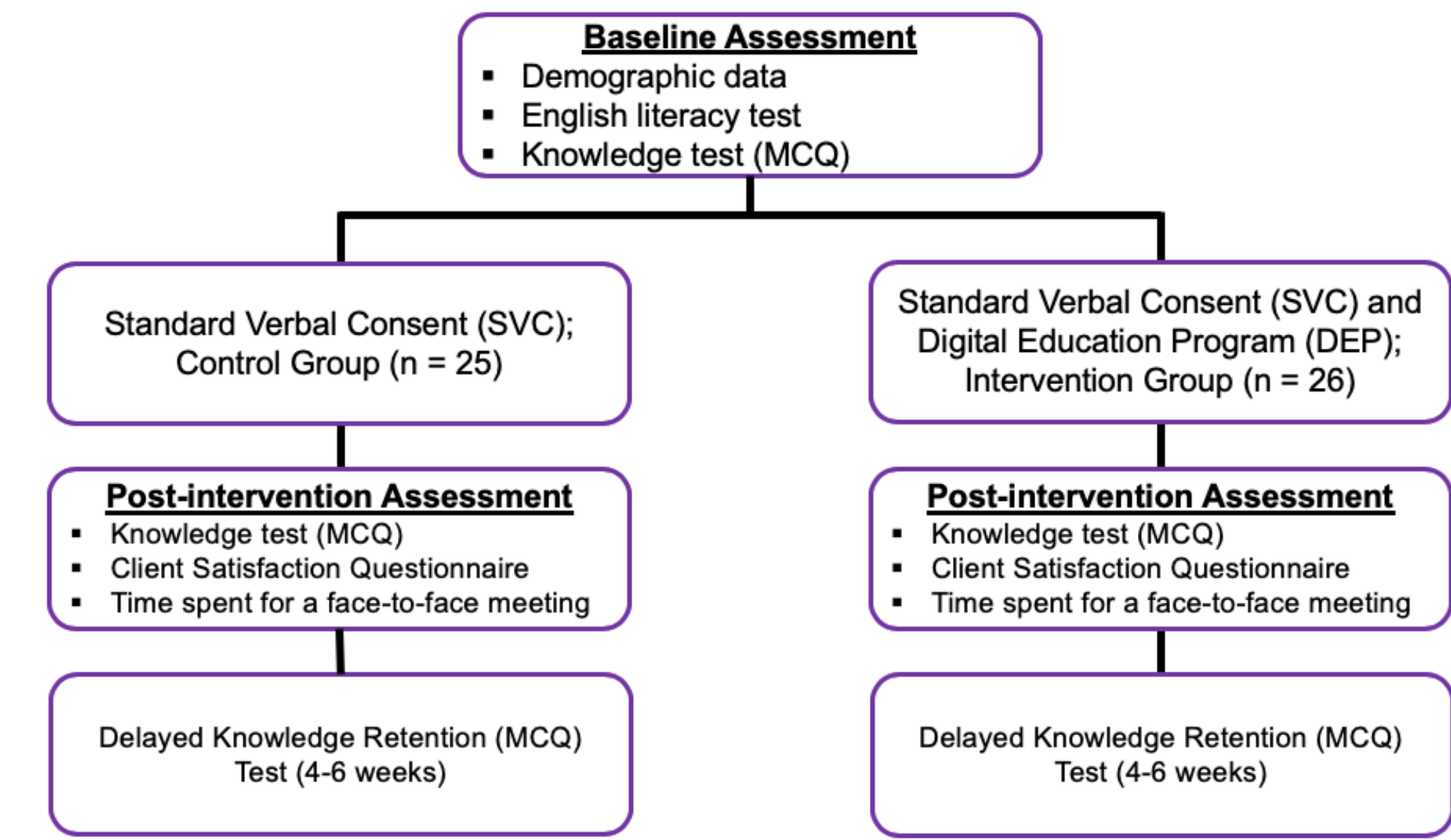


	Control (SVC) (n=25)	Intervention (SVC+DEP) (n=26)
Immediate satisfaction score (out of 32)	31	31.5
Delayed post-intervention assessment MCQ score (%)	82.9	84.4

Addition of a digital education platform to standard verbal consent for laparoscopic Roux-en-Y Gastric Bypass resulted in superior acquisition of knowledge, equivalent patient satisfaction, and over 50% time savings for the clinical encounter.



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Patient demographics:

	Control (SVC) (n=25)	Intervention (SVC+DEP) (n=26)
Age (mean)	45.6	43.4
Sex		
Male	0	7
Female	25	19
Highest Education		
No high school	1	3
High school	5	5
College/University	14	13
Postgraduate	5	5
Medical background	11	6
Seen a bariatric surgeon previously	3	2
English literacy test score (%)	96	88

Digital education platform:

There are **two major parts** of the operation:

- The stomach is made smaller with the use of stapling devices to ensure the top part of it is about the size of a small egg that holds only one ounce or 28 grams of food.
- Secondly the small bowel is divided so that about 150 cm of it is bypassed and food from the small stomach pouch goes directly into the small bowel farther down which reduces the absorption of calories and aids in the weight loss.



This video clip shows the creation of the re-entrancy of the bypassed length of small bowel further down using stapling instruments. The opening left from use of these devices is closed by a hand-sewn method. It is these staple lines and suturing points that can leak later on after surgery as listed in the next section about risks.

