Performance characteristics of unsedated ultrathin video endoscopy in the assessment of the upper GI tract: systematic review and meta-analysis

Sarmed S. Sami, MBChB, MRCP,[1] Venkataraman Subramanian, MD, DM, MRCP,[2] Jacobo Ortiz-Fernández-Sordo, MD,[1] Alhussain Saeed, MD,[1] Siddharth Singh, MD, MS,[3] Indra N. Guha, PhD,[1] Prasad G. Iyer, MD, MS,[4] Krish Ragunath, MD, MPhil, FRCP, FASGE[1]

Nottingham, Leeds, UK; Rochester, Minnesota, USA

Background and Aims: Reports on the performance of unsedated ultrathin endoscopy via the transnasal (uTNE) and transoral (uTOE) routes are conflicting. We aimed to estimate the technical success rate, patient preference, and acceptability of uTNE and uTOE alone and in comparison with conventional EGD (cEGD; with or without sedation).

Methods: A systematic review and meta-analysis was performed on all primary studies reporting the outcomes of interest. Electronic databases (Cochrane library, MEDLINE, EMBASE) were searched on February 1, 2014.

Results: Thirty-four studies met the inclusion criteria with 6659 patients in total. The pooled technical success rate was 94.0% for uTNE (95% confidence interval [CI], 91.6-95.8; 30 studies) and 97.8% for uTOE (95% CI, 95.6-98.9; 16 studies). The difference in proportion of success for uTNE compared with cEGD was –2.0% (95% CI, –4.0 to –1.0; 18 studies), but that difference was not significant when uTNE < 5.9 mm in diameter was used (–1.0%; 95% CI, –3.0 to .0; 9 studies). There was no significant difference in success rate between uTOE and cEGD (.0%; 95% CI, –1.0 to 2.0; 10 studies). The pooled difference in proportion of patients who preferred uTNE over cEGD was 63.0% (95% CI, 49.0-76.0; 10 studies), whereas preference for uTOE versus cEGD was not significantly different (38.0%; 95% CI, –4.0 to 80.0; 2 studies). Acceptability was high for both uTNE (85.2%; 95% CI, 79.1-89.9; 16 studies) and uTOE (88.7%; 95% CI, 82.4-92.9; 10 studies).

Conclusions: Technical success rate for uTNE < 5.9 mm is equivalent to cEGD. uTNE has high patient acceptability, with better patient preference, and therefore could be a useful alternative to cEGD for screening purposes. uTOE had a similar technical success rate but an equivocal preference to cEGD. (Gastrointest Endosc 2015;82:782-92.)

(footnotes appear on last page of article)

Unsedated ultrathin endoscopy techniques have been studied in an attempt to address some of the limitations of conventional EGD (cEGD) in terms of comfort, tolerability, and the need for sedation with costly monitoring and recovery facilities.[1] The use of unsedated ultrathin transnasal endoscopy (uTNE) was first reported in 1994.[2] Since then, many studies have yielded conflicting results with variable success rates ranging from 79%[3] to 99%.[4] Acceptability of uTNE also varied from as low as 9% to as high as 95% of patients willing to undergo the procedure again in the future.[5,6] Consequently, some investigators questioned whether it is the small diameter rather than the insertion route that might impact the procedure tolerance. Subsequent trials evaluating the tolerability of unsedated ultrathin transoral endoscopy (uTOE) have also reported inconsistent results.[7,8] Therefore, conclusive data on the performance of uTNE and uTOE remain lacking.

A technical status evaluation report from the American Society for Gastrointestinal Endoscopy has highlighted the need to assess the comparative effectiveness of the performance of ultrathin endoscopy instruments with standard size endoscopes.[9] The impact of unsedated ultrathin endoscopy on patient satisfaction was identified as an area that requires further research. Precise data estimates are therefore needed to help inform physicians, patients, and policymakers when making decisions regarding the implementation and use of this technology. The aims of

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this study were to estimate the technical success rate, patient preference, and acceptability of uTNE and uTOE either alone or in comparison with cEGD for diagnostic purposes. Differences in tolerability scores were also measured as a secondary outcome.

METHODS

This review was conducted according to a prespecified, peer-reviewed protocol based on the guidance provided by the *Cochrane Handbook for Systematic Reviews of Interventions*.[10] The study was reported according to the preferred reporting items for systematic reviews and meta-analyses, or PRISMA, statement.[11]

Search strategy

A literature search was conducted using OVID MEDLINE (1946 to February 2014), OVID EMBASE (1974 to February 2014), and the Cochrane Central Register of Controlled Trials. Other sources searched included reference lists of identified primary journal articles and abstract books of conference proceedings, namely the British Society of Gastroenterology conference, United European Gastroenterology Week, and Digestive Disease Week between 2002 and 2013 to identify potentially eligible studies.

The following combination of terms was used (both as free text and, where applicable, as Medical Subject Headings): (endoscop* OR gastroscop* OR oesophagogastroduodenoscop* OR esophagogastroduodenoscop* OR ogd OR egd OR esophagoscop* OR oesophagoscop*) AND (super-thin OR superthin OR small-calibre OR small-caliber OR ultrathin OR ultra-thin OR nasal OR transnasal OR trans-nasal OR unsedated OR un-sedated OR office). No limits or restrictions were applied.

Study selection and outcome assessment

Studies were eligible if they included adult patients, aged 18 years or older, and reported data on the performance of diagnostic uTNE or uTOE either alone or in comparison with cEGD (with or without sedation) with regard to any of the 4 study outcome measures:

- Technical success rate: calculated as the proportion of patients in whom the procedures were completed out of total procedures attempted for each modality (uTNE, uTOE, and cEGD). Completion was defined as achieving the intended extent of examination.
- Preference: defined as the proportion of subjects who preferred uTNE versus cEGD or uTOE versus cEGD. Subjects in those studies had undergone both uTNE (or uTOE) and cEGD procedures and were then asked which one they preferred or would choose to undergo again in the future if clinically indicated.
- Acceptability: measured as the proportion of patients who had either uTNE or uTOE and expressed willingness, when asked, to undergo the same procedure again in the future if clinically indicated.
- Tolerability: calculated from the visual analogue scale reported for each study.

Studies were excluded if they reported data on therapeutic procedures or nonrelevant outcomes, used fiberoptic endoscopes, or published in non-English language. An insertion diameter of 6.5 mm or less was defined as ultrathin for the purposes of this study based on current literature.[9]

Data extraction and quality assessment

Two reviewers (S.S.S. and J.O.) independently screened titles and abstracts identified by the primary searches to identity potentially eligible studies, of which the full-text articles were read and assessed for inclusion. Data from included studies were independently extracted by the 2 investigators (S.S.S. and J.O.) and entered into a standardized Microsoft Excel spreadsheet pro-forma (Excel 2010; Microsoft, Redmond, Wash). Any differences between the data sets were resolved by discussion, and if disagreement persisted, a third party (V.S.) was consulted. Whenever applicable, the authors of primary articles were contacted and asked to supply any missing data.

The following variables were extracted for each study: year of publication, setting, number of centers, country of origin, study design, population studied (symptoms, age, sex, sample size), devices used (make, model, insertion diameter), and procedure details (insertion route, sedation use, extent of examination, operator experience, adverse events). Data were extracted on an intention-to-treat basis, with dropouts assumed to be procedure failures, whenever trial reporting allowed. Study quality was assessed independently by 2 investigators (S.S.S. and J.O.) using the Cochrane Collaboration's tool for assessing risk of bias[12] (for randomized controlled trials) and the modified Newcastle-Ottawa Scale[13] (for nonrandomized 2-cohort and single-cohort studies).

Statistical analysis

The DerSimonian-Laird Random effects model[14] was used to calculate with 95% confidence intervals (CIs) (1) the pooled proportion of the technical success rate of uTNE and uTOE alone, (2) the risk difference (RD) for the technical success rate between both uTNE versus cEGD and uTOE versus cEGD, (3) the RD for the preference rate between both uTNE versus cEGD and uTOE versus cEGD, (4) the pooled proportion of the acceptability rate for uTNE and uTOE alone, and (5) the standardized mean difference (SMD) in tolerability scores between both uTNE versus cEGD and uTOE versus cEGD. There was a variation in the range of scales used to measure tolerability among studies (eg, 1-5, 0-10, 0-100); hence, the SMD summary statistic was used to account for this variation. Whenever reported, the values of mean score and standard deviation were extracted for each study. In other circumstances, we used validated formulas to calculate these values from the reported