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Systematic Review of Effectiveness and Safety of Wireless pH Capsules and pH Catheters in the Monitoring of Gastroesophageal Reflux

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ADMINISTRATIVE INFORMATION

Support - Drug Regulatory Science Project of Gansu Provincial Drug Administration(2022GSMPA0016, 2022GSMPA0015).

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202490021

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 6 September 2024 and was last updated on 6 September 2024.

INTRODUCTION

Review question / Objective Patients with reflux symptoms who test negative on endoscopy often require further confirmation with nasal pH probes, but whether wireless pH capsules are more effective, safe, and comfortable than probes needs to be clarified.

Rationale In terms of detecting esophageal acid exposure, the sensitivity of pH catheter monitoring is 70-80%. But the device has adverse events including discomfort in the nose or pharynx and displacement of the pressure-sensing location. Wireless pH capsules not only can extend the pH monitoring time to ≥48 h, but their sensitivity is also comparable or better than that of traditional catheter pH monitoring systems at 70-80%. However, there are some inconsistent reports on the tolerability of wireless pH capsules in patients, and there is a lack of validated questionnaires to objectively assess the level of interference from daily activities. Therefore, it is necessary to objectively evaluate the diagnostic efficacy, interference from daily activities, and adverse events of Bravo pH wireless capsules.

Condition being studied The 24-hour pH monitoring has been the standard treatment for diagnosing PPI-refractory GERD patients, but the device has adverse events including nasal or pharyngeal discomfort and catheter displacement at the pressure-measuring site. Wireless pH capsules were developed to overcome some limitations of catheter-based pH monitoring. However, there have been inconsistent reports of patient tolerance for wireless pH capsules, and there is a lack of validated questionnaires to objectively assess the level of interference with daily activities. Therefore, we conducted a meta-analysis and systematic review of wireless pH capsule use in GERD reflux monitoring, using the nasopharyngeal pH catheter as the "gold standard," to objectively evaluate the diagnostic efficacy, interference with daily activities, and adverse events of wireless pH capsules.

METHODS

Search strategy

#1 wireless capsule
#2 Bravo capsule
#3 pH capsule
#4 wireless pH monitoring
#5 capsule pH monitoring
#6 #1 OR #2 OR #3 OR #4 OR #5
#7 pH catheter
#8 pH metry
#9 pH-impedance
#10 pH monitoring catheter
#11 pH monitoring metry
#12 catheter-based pH impedance
#13 esophageal pH monitoring
#14 #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13
#15 #6 AND #14
We will search articles in five electronic databases including PubMed, Web of Science, Embase, Cochrane Library and China National Knowledge Infrastructure. All publications prior to 9 september 2024 will be searched without any country or article type restrictions. The reference lists of all selected articles will be independently screened to identify additional studies that were missed in the initial search.
The search will be re-run prior to final analysis and any identified, retrieved further studies.
Attempt to seek unpublished research.

Participant or population Patients suspected of having gastroesophageal reflux disease (GERD) or those undergoing preoperative evaluation requiring ambulatory reflux monitoring.

Intervention Reflux monitoring by wireless pH capsule.

Comparator Reflux monitoring by conventional catheter (pH/pH-impedance(MII-pH) catheter).

Study designs to be included RCTs that randomized patients to Bravo versus Conventional catheter group or crossover studies comparing the interference with daily activities and adverse events between Bravo wireless capsules versus conventional catheter-based system.

Eligibility criteria Inclusion criteria: Age ≥ 18 yr and ≤ 65 yr; Typical symptoms: regurgitation and heartburn; Atypical symptoms: belching, chest pain, pharyngeal burning, foreign body sensations, chronic unexplained pharyngitis, hoarseness; bronchitis, and asthma; Proton pump inhibitor therapy-positive; Written informed consent.

Exclusion criteria: Nasopharynx or upper esophagus obstruction; Esophageal varices and severe esophageal mucosal erosion; Severe esophageal motility disorder (e.g., achalaisa, scleroderma, diabetes mellitus, autonomic or peripheral neuropathy, and myopathy); In vivo congenital gastrointestinal malformation, gastrointestinal obstruction, perforation, stricture, or fistula; A recent history of stomach surgery or gastrointestinal bleeding (within the past 6 mo); A history of bleeding tendency and taking anticoagulant drugs in the long term; Any implanted electrical device, such as cardiac pacemakers; Allergy to the polymer materials; Various acute enteritis, severe ischemic disease, or radioactive colitis.
Pregnancy/lactation; Unstable cardiopathy, psychotic diseases arrhythmia cordis, or being uncooperative.

Information sources We will search articles in five electronic databases including PubMed, Web of Science, Embase, Cochrane Library and China National Knowledge Infrastructure. All publications prior to 9 september 2024 will be searched without any country or article type restrictions. The reference lists of all selected articles will be independently screened to identify additional studies that were missed in the initial search.
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Main outcome(s) 1.Interference with daily activities; 2. Adverse events(nasal, throat, chest);3.Patient preference;4.Technical Efficacy.

Additional outcome(s) Not applicable.

Data management Not applicable.

Quality assessment / Risk of bias analysis Two evaluators independently assessed the risk of bias in the included studies and cross-checked their results. Disagreements were resolved through discussion with a third party. The risk of bias in RCTs was assessed using the recommended tools for bias assessment in the Cochrane Handbook 5.1.0. The risk of bias in Non-RCTs was assessed using the methodological index for non-randomized studies (MINORS).

Strategy of data synthesis The statistical analysis was conducted using RevMan 5.3. Continuous data were analyzed using the mean difference (MD) or standardized mean difference (SMD) as the effect measure, while dichotomous data were analyzed using the relative risk (RR) as the effect

measure. All effect measures were accompanied by their 95% confidence intervals (CI). Heterogeneity among the included studies was analyzed using the χ^2 test (α=0.1), and the magnitude of heterogeneity was quantitatively assessed using I^2. If no statistical heterogeneity was found among the included studies, a fixed-effect model was used for the meta-analysis. If statistical heterogeneity was found, the source of heterogeneity was further analyzed, and a random-effects model was used for the meta-analysis after excluding the obvious clinical heterogeneity. The significance level for the meta-analysis was set at α=0.05. Obvious clinical heterogeneity was handled using subgroup analysis or sensitivity analysis, or only descriptive analysis was performed.

Subgroup analysis Subgroup analysis was conducted based on age and duration of reflux monitoring in the included population.

Sensitivity analysis Not applicable.

Language restriction English and Chinese.

Country(ies) involved China.

Other relevant information Not applicable

Keywords GERD, Ambulatory monitoring, wireless pH capsule.

Dissemination plans Artical submission and academic dissertation.

Contributions of each author

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