International
Continence Society

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ICS position statement: "Renew Insert" – a new product to alleviate accidental bowel leakage

ICS position statement based on a summary evidence synthesis by ICS member Julia Herbert (Consultant Physiotherapist, UK)

Executive Summary

Accidental bowel leakage (ABL) could be described as the 'Cinderella' topic in the world of the treatment and management of incontinence. Whilst there have been significant developments in the speciality of urinary incontinence, anal incontinence has not attracted such investment with relatively little in the way of new products to help those affected by this 'taboo' condition. Renew Medical have developed a new product designed to help manage accidental bowel leakage. The Renew Insert ® is a discreet, easy-to-use device that is designed for self-insertion to comfortably seal the rectum from the inside. Clinical studies in the United States have demonstrated that the Renew Insert is safe to use and that the device reduces Accidental Bowel Leakage by nearly 82%. A UK consumer panel of Renew Insert has also rated overall satisfaction at 4.8 out of 5.

Renew Inserts

Anal incontinence is still considered a major taboo amongst those that suffer from accidental bowel leakage (ABL). It is known that prevalence rates vary related to how the severity of the leakage is reported, however it is estimated by the Bladder and Bowel Foundation (UK) that as many as 1 in 10 adults may suffer from anal incontinence. Higher prevalence rates of 18.8% were recorded in a study of almost 6,000 US women aged 45 years or older; the Mature Women's Health Study [1].
Conservative therapy such as anal sphincter exercises, biofeedback and electrical stimulation will benefit some patients however their remains a need for those who still experience accidental bowel leakage to have access to effective management strategies. Incontinence pads are not well suited to the management of leakage from the bowel as they are unable to fit closely to the anal verge allowing faecal material to leak onto the skin, increasing the risk of odour and staining of the clothing. Anal plugs have been available for a number of years and whilst they can significantly improve the quality of life for some people there are difficulties for many in tolerating the plug. There have been no new developments in this area for some time. Renew Medical are now launching a new product aimed at accidental bowel leakage called the 'Renew insert'. The Renew insert is a silicone anal insert, designed for self-insertion to comfortably seal the rectum from the inside to help prevent accidental bowel leakage. The insert is provided with an applicator which assists the user to correctly position the device in the anal canal.

Clinical data

Data included in this report has been provided by Renew Medical.

REST study

The clinical evidence supporting Renew Inserts includes a US pivotal study which is not yet published but has been submitted for publication.
REST[2] is a study to evaluate the safety, tolerability and effectiveness of the Renew insert in treating accidental bowel leakage. This was a multicentre, prospective, single-arm, non-randomised pivotal study designed to establish the safety, effectiveness, and tolerability of the Renew insert in patients with moderate-to severe bowel incontinence (defined as having a Wexner score greater than 12).

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The primary aims of this study are stated as the assessment of ABL frequency and post treatment Wexner scores. The study also had safety endpoints to assess Insert related serious adverse events (primary) and whether there was any anal canal or lower rectal mucosal irritation from the use of the Insert during the study period (secondary).

A cohort of 97 patients, ≥18 years old with ABL severity score ≥12/20, and at least weekly leakage of solid and/or liquid stool, was recruited to a 4 week baseline period during which the degree of ABL was assessed. There were 6 dropouts during the baseline phase, 4 due to not meeting the eligibility criteria and 2 who found the protocol too demanding. A total of 91 patients entered the treatment phase comprising of 90.1% females with a mean age of 68.6 years (range from 33.9 to 88.9 years). This 'Intent to treat' cohort (ITT) also formed a safety cohort. The ITT cohort used at least 1 Insert during the treatment phase, however there were 6 patients who discontinued during the first week; 2 found the protocol too demanding, 2 had pre-existing haemorrhoids which made Insert use uncomfortable and 2 who experienced loss of the Insert during urination or due to excess anal mucous. A total of 85 patients used the Renew insert for at least 1 week forming the Modified ITT cohort.

Main outcome measures.

These are reported as including Bowel diaries, ABL severity, adverse events, and satisfaction. Percent reduction in leakage frequency and ABL severity were assessed. Sample size calculations estimated 76 subjects would detect a 10% reduction in ABL frequency with 90% power. Paired T-test and Wilcoxon tests were used as appropriate.

Results

During the pre-treatment baseline period, ABL frequency was about 8 ABL episodes per week (daily mean of 1.12 ± SD 0.849 / median 0.89 per day). After treatment with Renew Inserts ABL was reduced to about 1 ABL episode per week (daily mean of 0.29 ± SD 0.376 / median 0.17 and a median ABL reduction of 81.8% as compared to the baseline period ($p<0.001$). 78% of subjects had ≥50% reduction in ABL frequency.

Reduction in Wexner score was analysed on 77 patients who had both a pre-treatment and post treatment Wexner score. Pre-treatment the median Wexner Score was 16.0 which was reduced post treatment to 11.0, demonstrating a 29.4% median reduction in the Wexner score. Company literature reports mean Wexner scores as improving by 32.4% (16.2, +/-2.1 vs. 10.9, +/-4.4 out of 20, $p<0.001$).

Safety analysis

Safety was evaluated on the 91 patients in the ITT cohort. Over 50% of patients experienced some adverse events (AE) with 64.6% of the events assessed by the investigators as 'probable' or 'possible' related to the device. There were no events rated as severe, nor were there any reported serious, unanticipated events. Almost all (98.7%) of these 'possible' device related events were rated as 'mild' and included, anorectal urge (26.4%) or irritation (13.2%), GI discomfort (4.4%) or gas (3.,4%) and haemorrhoids (5.5%).

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In addition to these reported adverse events 24% of patients reported device displacement where the bottom disc of the device migrated into the anal canal. Where these occurred they are reported as predominantly being resolved by natural expulsion during subsequent bowel movements. Pre-treatment and end treatment anal canal and lower rectal mucosa evaluations were performed on 77 patients. 8 patients could not or would not attend to have an end of treatment rectal examination. End of treatment anal canal and lower rectal mucosa evaluation showed normal digital rectal exams in 100% of subjects. Anoscopic rectal exam results were normal in 97.4% of subjects, and 2.6% of the treated subjects were found with abnormal exams which were determined to be not device related.

Summary

The REST pivotal study demonstrates a significant reduction in the incidence of ABL with significant reductions in Wexner scores. The safety data has demonstrated that the device is safe to use. The reported overall satisfaction among the majority of Insert users was high, with 91.4% rating overall experience and ease of use rated as a 9.5 (median) on a 10 point scale.

Usability study: 35 month UK consumer panel[3]

A user evaluation is reported in the company Medical Clinical Summary data sheet.
This study was conducted in the UK and included females ≥ 30 years old with daily/weekly ABL and a total Wexner score of > 14, who had no severe or complicating pre-existing medical conditions that could impede usage of Renew Inserts. 19 subjects consented to participate in continuous use of the device with 11 completing the 35 month test.

Results

Users consistently reported an extremely high level of satisfaction with Renew Inserts with a 35 month average rating of 4.8 on a 5-point scale, where 5 is extremely satisfied. With regard to ease of insertion users reported an average of 9.5 on a 10 point scale, where is 'straight forward, simple and comfortable, resulting in an overall very positive experience.

There was an average 69% decrease in total Wexner scores which comprised of an 80% decrease in the scores for incontinence of solid faces, 83% decrease in the frequency of using pads to manage their condition and a 75% decrease in the extent to which the condition impacted on their quality of life.

The users are reported to have scored the Instruction for Use (IFU) and Frequently asked Questions (FAQ) over a 24 month period with an average of 4.9 where 5 is' extremely easy to understand'. Most users reported that they did consult the IFU during the first month of use, but thereafter referred back to it only intermittently and primarily only during the first 6 months of use.

Usage issues

There were 6 complaints reported during the 35 month period which were attributed to the performance of the Renew Insert (3 of which reported by same user). None of these were considered reportable adverse events.

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Conclusion

The data presented in this review of a pivotal non-randomised single -arm study appears to demonstrate clinically significant improvement for patients with accidental bowel leakage using Renew Inserts; however this data has not yet been published and therefore has not been subject to peer review. Clinical outcome results are reported for the Modified ITT cohort and whilst there were some dropouts from the original cohort, the study population of 85 patients still exceeded the sample size calculation of the 76 estimated to be required to detect a 10% reduction in ABL frequency with 90% power.

There are limitations to this study in that it does not compare the use of Renew Inserts to other treatment / management strategies so it does not inform if this product gives significant advantage over existing products. It is also a US based study with no demographic data reported so it is difficult to assess its transferability to other populations.

Existing data on the use of anal devices to prevent accidental bowel leakage is limited. The 2012 Cochrane review reports on only 4 studies for which the most recent of which were not published until 2007, (Pfrommer 2000; Norton 2001; Van Winckel 2005 and Bond 2005*[7]).

The conclusion of the Cochrane review is that the trials whilst demonstrating clinical benefit to users were mostly of varied quality and demonstrated that anal plugs can be difficult to tolerate. The REST study demonstrates an improvement in tolerability of the Renew Insert device above that seen with anal plugs with only 7% drop out rate versus anal plugs which varied from 25% – 68%.

The data presented in the UK usability study contains a disappointing number of participants with an apparently higher dropout rate than the US study. No detailed data was available about this study at the time of this review. It is therefore difficult to draw conclusions about the use of this product with a UK population. Whilst the usability outcomes showed a high performance of the device with such small numbers it is not possible to evaluate the clinical outcome results.

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Renew press release 2015

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Other resources:
www.bladderandbowelfoundation.org