Review of the Clinical Evidence for IODOSORB and IODOFLEX° in Peer Review Journals

A literature review was conducted of the clinical evidence available for Cadexomer Iodine based products and a comparison of the data is presented below using the CERT literature review tool.

Methods
The literature search was carried out on databases; Medline Embase, Cinahl and Scisearch using IODOSORB, IODOFLEX and Cadexomer Iodine as key words. The search resulted in 65 papers, only 20 of which were included in the CERT analysis. This included full articles in English, on studies of patients only. The exclusions were any papers on in vitro or animal work, those in other languages and any other papers which were not full journal articles.

The CERT (Clinical Evidence Review Tool) analysis involved scoring each paper out of 20 on key aspects of study methodology such as clarity of objectives, appropriateness of measures, number of patients and quality of the statistical analysis conducted. This effectively differentiates between good quality “clinical trials” which typically score around 15/20 and single case studies which score around 3/20. The quality score was assigned a positive value if the study favoured the product, and a negative value if the results favoured the comparator or where there was no clinical difference reported. For comparative studies, the scores were entered separately for each product. This enabled a separate analysis of each product independent of the comparator used.

The scores for all papers were plotted on a bar chart with one bar per product. The number on the x-axis of the bar chart identifies the reference number of the paper in the reference list attached.

Of the 20 papers included in the CERT analysis, 16 were on the use of IODOSORB on patients; 2 on IODOFLEX (a Smith & Nephew trademark for IODOSORB dressing) and 2 where the product used was termed Cadexomer Iodine, with no specification as to whether it was IODOSORB or IODOFLEX.
IODOSORB
The results of the CERT analysis of the papers, which reported on the use of IODOSORB, can be seen in Figure 1.

Of the 16 full articles on IODOSORB, 13 were positive and the majority of these were on chronic venous leg ulcers with 1 on diabetic foot ulcers. In this case a positive score indicated that IODOSORB was a more effective treatment than Garamycin™, Varidase™ and dry saline gauze. In the other 12 papers with a positive effectiveness score, IODOSORB was more effective than its comparators in the treatment of chronic venous leg ulcers where the comparators included:

- Debrisan™ (2 papers)
- Standard treatment (5 papers)

Standard treatment consisted of various dressings, including MELOLIN®, Non-adherent dressings plus support bandages, paraffin impregnated gauze, Gentian Violet and Polyfax™ ointment. Various dressings/products including: enzyme preparations, dextranomer, fusidic acid, trypure powder, polymixin and silver nitrate, Duoderm E™ and JELONET®, Zinc paste dressings, and wet-to-dry saline soaked gauze.

There were 2 papers where there was no comparator but a positive score was given on the basis of the overall conclusions of the paper.

The 3 IODOSORB papers that scored negatively were good quality papers (scoring 10, 12 and 13) but for the end points measured, their comparators performed better than IODOSORB in the treatment of venous leg ulcers. The comparators were Dextranomer™, Debrisan™ and various standard treatments including: topical antibiotics, antiseptics, hydrophilic agents, bland agents, steroids and dry dressings.

Figure 1 shows that the quality of the papers on IODOSORB is variable, however 14 achieved an effectiveness score of 10 or above, indicating generally good quality papers. The 2 papers that scored less well were one case study (chart number 20, score = 3) and one non-comparative study with low patient numbers (chart number 8, score = 8).
The graph showing the results of the CERT analysis on IODOSORB, IODOFLEX and Cadexomer Iodine can be seen in figure 2. The 2 papers on the use of IODOFLEX were both in the treatment of venous leg ulcers, one with a score of 3 (chart number 1) and the other with a score of 9 (chart number 3). The scores were low as neither study compared IODOFLEX against another product. In this case the scores were positive with IODOFLEX, achieving a positive outcome for the endpoints in each study.

**Cadexomer Iodine**

There were 2 papers using Cadexomer Iodine where IODOSORB or IODOFLEX was not specified. The first was used in the treatment of pressure ulcers and was a good quality paper (chart number 14, score = 11) where Cadexomer Iodine was shown to be a more effective treatment than its competitor: a standard treatment of saline dressings; enzyme based debriding agents and/or non-adhesive dressings depending on the ulcer.

The other paper on Cadexomer Iodine reported on its use in the treatment of Pyoderma Gangrenosum where Cadexomer Iodine was used as a treatment in conjunction with bioengineered skin and antibiotic therapy. This was found to be a positive treatment for the endpoints, but had a low score (chart number 16, score = 6), as there was no comparator.
Figure 2: Graph of all IODOSORB, IODOFLEX and Cadexomer Iodine Results.

Conclusions

From the CERT analysis carried out it can be seen that:

- More clinical evidence for IODOSORB than IODOFLEX
- The evidence supports the use of both products
- The quality of the majority of the evidence was better for IODOSORB than for the 2 papers on IODOFLEX.

Given the overall positive results and the generally good quality of the papers reviewed, it may be beneficial to carry out a similar analysis of the competitors for IODOSORB.

It should be noted that this document only reviews papers indexed in the databases searched on the 27th July 2004. Carrying out new literature searches to capture articles indexed after this date is recommended.

References


Local prescribing information to be inserted here

° Trademarks of Smith & Nephew
™ All trademarks acknowledged