

I. UNIV.-KLINIK FÜR CHIRURGIE

Director: Univ.-Prof. Dr. Franz Gschnitzer
DEPARTMENT FOR PAEDIATRIC SURGERY
Head: Prim. Doz. Dr. G. Menardi

A-6020 Innsbruck, 23.04.1998
Anichstrasse 35
Tel. 0512-504/2534

Dr. Jörg Siebert
Schülke & Mayr GmbH
Robert-Koch-Str. 2
22840 Norderstedt

Subject: Use of OCTENISEPT for pre-operative skin and mucous membrane antiseptics and for supportive wound and suture treatment in small children and babies
Observational use study

1. Question

Octenisept is an antiseptic that was approved and introduced several years ago, and which is used prior to surgical procedures, diagnostic procedures on skin and mucous membrane, and for supportive wound treatment.

Tolerability in children has been verified by means of clinical investigation and by a number of experience reports, but these included only a limited number of small children and babies.

The objective of this prospective observational use study was to document the use of Octenisept in predominantly small children and babies systematically over a certain period, in order to document the experiences with the preparation in this age group also.

In this study, in addition to pre-operative skin antiseptics, OCTENISEPT was mainly used for postoperative wound and suture care, for which an aqueous preparation was to be used in preference to an alcohol-based skin antiseptic for reasons of tolerability.

2. Patient clientele

A total of 68 children were included in this prospective observational use study between 24 October and 28 November 1997. As a result of the limited period of the data collection, equal distribution of the sexes was not possible. The majority of children in the study period were boys (47), while in the same period only 21 girls were treated with Octenisept.

For each patient a case report form (see annex 1) was completed, which included the most important data on the patient, the diagnosis and the treatment, and the reactions to the use of Octenisept.

The age distribution is given in the following table:

Table 1: Age distribution

Age group	Number
0 – 6 months	20
7 – 12 months	3
1 – 3 years	11
4 – 6 years	15
7 – 8 years	9
> 8 years	10

3. Use

The preparation was used in septic and aseptic operations for skin and wound disinfection and also prior to post-operative changes of dressing.

The most frequent uses of Octenisept were pre-operatively before appendix operations (20) and hernia operations (18) and for the subsequent dressing changes.

A list of all procedures in which Octenisept was used can be seen from the following table.

Table 2: Nature and frequency of the surgical procedures

	male	female
New creation of anastomosis	1	-
Appendectomy	11	9
Hernia	16	2
Hernia and hydrocele	4	-
Umbilical hernia	-	1
Umb. hernia + hydrocele	1	-
Ileus	1	-
Colostomy re-operation	1	-
Cryptochism	2	-
Muscle biopsy	1	1
Scar revision	1	-
Phimosis	5	-
Insertion of port-a-cath.	1	2
Sept. surgery	1	5
Valve revision	1	1
TOTAL	47	21

The preparation was used pre-operatively in all patients, in all cases applied with swabs soaked in Octenisept (swab size 7.5 x 8.5 cm). Whereas in general the use of 2 swabs was sufficient, in the case of appendectomies a third swab soaked in Octenisept was also used intraperitoneally before closure of the wound for disinfection of the appendix resection site. This type of use is noted on the case report forms under point 2 of the “indications”.

In 24 patients the preparation was used once, in 21 patients twice, and in 23 patients three times. In the cases of use more than once, as well as on the day of the operation it was used when the dressing was changed (in general after 24 hours) and on the day of discharge for wound and scar treatment. Also in these cases the preparation was always applied with a swab to the area of the body being treated.

4. Results

From the medical point of view no reactions such as swelling, redness, allergic reaction, papules or weeping were observed during the observation period of 4 to 24 hours after use of the preparation. The observation period was determined by the length of the outpatient or inpatient treatment.

Nor, as far as could be determined in this patient population, could any subjective discomfort such as pain, burning sensation or itching occur that could be related directly to the antiseptic.

During the period of hospitalisation, no cases of wound infection were observed, although procedures susceptible to infection (e.g. valve revision in cases of hydrocephalus, insertion of a port-a-catheter) fell in the time of this observational use study.

A summary of all patients and data entered on the case report forms is to be found in annex 2.

5. Conclusion

This systematic collection of data on the use of Octenisept prior to surgical procedures and for wound treatment also confirms in small children and babies the good local tolerability of the preparation observed in practice. In our opinion use in this age group can be approved without reservation.

The good local tolerability is to be valued all the more highly, as a local antiseptic that is safe for this age group previously did not exist.

However, until there is evidence to the contrary, premature infants must be excluded from this evaluation on account of the absence of data.

Prim. Doz. Dr. G. Menardi

Specialist Dr. med. H. Fuchs

+ Annexes 1 and 2