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Topical antiseptic mouthwash in oncological surgery of the oral cavity and oropharynx

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Abstract

A multivariant analysis of the value of the use of a pre-operative topical antiseptic mouthwash to reduce the incidence of post-operative wound complications in 106 consecutive patients undergoing head and neck surgery involving the oral cavity or oropharynx was carried out at the University of Iowa, Department of Otolaryngology–Head and Neck Surgery. An oral presentation employing povidone–iodine solution was used for 43 patients. The remaining 63 patients studied received no oral presentation. Unfavourable wound outcome was not associated with age, sex, presence and condition of teeth, or serious pre-existing medical illnesses. A significant correlation was found between post-operative wound breakdown and type of closure, stage of disease, and previous operation or radiotherapy. The use of an oral preparation correlated significantly with favourable wound outcome independent of all other variables ($p<0.01$).

Our data support the use of a topical antiseptic mouthwash to reduce the incidence of post-operative wound complications in surgery of the oral cavity and oropharynx.

Key words: Oral hygiene; Mouth neoplasms; Oropharyngeal neoplasms; Surgery, complications

Introduction

The rate of wound complications in surgery of the upper aerodigestive tract was very high before the use of perioperative intravenous antibiotics (Dor and Klastersky, 1973; Becker and Parell, 1979). Large, controlled patient series have delineated the optimal timing and duration of the administration of intravenous antibiotics in head and neck cancer surgery (Johnson *et al.*, 1986). However, the efficacy of topical antibiotics or antiseptic preparations remain unclear.

Large series in other organ systems, such as in colonic surgery, have shown topical preparations to be equal to, or better than, intravenous antibiotics in preventing post-operative complications (Condon *et al.*, 1979; Condon *et al.*, 1983). In oral and oropharyngeal surgery, some studies show no effect of topical antibiotics on wound complications (Breloff and Caffesse, 1983; Jones *et al.*, 1989), while others show marked efficacy (Robinson, 1976; Barton and Moir, 1983). Similarly, some studies show reduction of intra-operative oral bacterial counts and bacteraemia with the use of topical antiseptics (Scopp and Orvieto, 1971; Exner *et al.*, 1985; Jones *et al.*, 1989), while others show no change in bactaeremia (Huffman *et al.*, 1974).

Common among all these series is the small sample size ranging from 12 to 22 patients (Huffman *et al.*, 1974; Robinson, 1976; Barton and Moir, 1983; Breloff and Caffesse, 1983; Jones *et al.*, 1989). One of these series (Barton and Moir, 1983) had no control group. In many (Scopp and Orvieto, 1971; Huffman *et al.*, 1974; Robinson, 1976; Breloff and Caffesse, 1983; Jones *et al.*, 1989), the distribution of risk factors for wound complications is unclear. Therefore, we present a study of wound outcome in 106 consecutive patients undergoing head and neck oral and oropharyngeal operations. Forty-three of these patients received standardized pre-operative oral preparations. Other risk factors for wound outcome were tabulated. This patient series was large enough, and risk factors were distributed equally enough, to adequately establish the efficacy of pre-operative antiseptic preparations in reducing wound complications.

Materials and methods

Patients undergoing 106 consecutive oral cavity and oropharyngeal operations were assigned to one or the other arm of the study, and their wounds were evaluated retrospectively through chart review. Data gathered were age, sex, location and stage of disease, tumour type, previous medical illnesses, previous radiation, chemotherapy or surgery, presence and condition of the teeth, type of closure, and whether a pre-operative antiseptic mouth preparation was administered.

Significant previous medical illnesses were those ill-

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nesses which were thought to potentially affect wound outcome. These are listed on Table I. The teeth were examined and assessed by either a prosthedontist or an oral surgeon, and graded as edentulous, or teeth present and in good condition, or teeth present and in bad condition. Type of wound closure was primary closure, pedicled flap, or free flap.

The oral topical antiseptic preparation was administered directly after induction and tracheal intubation. A throat gag was put in place, and three rinses of 10 per cent povidone–iodine were given, accompanied by scrubbing into the gingival sulci and oropharyngeal mucosa with soft sponges. This povidine–iodine scrub was followed by a single 500 cc saline rinse.

Assignment of the patient to the oral preparation was based upon the last digit of the patient's hospital identification number. However, this policy was difficult to administer consistently among the University's many surgeons, and therefore many patients were entered into the incorrect arm of the study. In only one case did the patient receive a mouthwash on the basis of any individual surgeon's policy.

Almost all patients received pre-operative and post-operative intravenous antibiotics. Antibiotics given were anti-staphylococcal, anti-anaerobic, and occasionally anti-gram-negative.

Post-operative wounds were evaluated by resident and staff physicians without knowledge of the mouthwash group assignment. Grading of the wound complications was performed by the authors, using the written description of the wound. The patients had been assigned to treatment arms pre-operatively. However, since chart review was used to grade their post-operative wounds, their actual wound evaluation was a retrospective one. This grading was performed independently by both authors, and was also done without knowledge of the mouthwash assignment group. Wounds were graded as normal healing, small wound complications, and large wound complication. The grading of the wound was weighted toward infectious complications, so that complications which did not appear to be infectious were graded as small. A large wound complication was defined as one which required a second procedure, or prolonged the hospital stay. Table II lists the complications seen. The two grading lists were then compared, and 83 per cent agreement in wound classification was found. The 18 instances of disagreement were resolved by re-examination of the written description in 13 cases (72 per cent) or by re-applying the criteria of large and small wounds in five cases (28 per cent) (Table III). Six wounds received a more favourable wound classification in this process. These six were distributed as three in the mouthwash group, and three in the non-mouthwash group. Twelve wounds received a less favourable wound classification, and these were distributed as five in the mouthwash group (42 per cent) and seven in the non-mouthwash group (58 per cent). This compares to 43 patients in the mouthwash group (41 per cent) and 63 in the non-mouthwash group (59 per cent).

Sequential statistical analyses were performed. First was an examination for potential bias in the distribution of possible risk factors between the treatment and control groups. Then the distribution of the wound outcome variables between the treatment and control groups was evaluated. Regression analysis was used to identify any association between the wound outcome variables and each risk factor. Finally, the distribution of wound outcome variables and of risk factors were evaluated for interactions.

TABLE I

PRE-EXISTING MEDICAL ILLNESSES POTENTIALLY AFFECTING WOUND HEALING

Illness	Number of patients
Coronary artery disease/myocardial infarction/arrhythmias	7
Diabetes	4
Hypertension	3
Peripheral vascular disease	3
Hypothyroidism	2
Chronic obstructive pulmonary disease	2
Cerebrosvascular accident/quadriplegia	2
Atypical TB–lung, previous prostrate cancer, colon cancer, esophageal cancer, liver failure with ascites and peritonitis, anaemia, hypercoagulable state	1 each

Results

Distribution of risk factors

Forty-three patients received the mouth preparation, and 63 did not. Statistical analysis found no differences between the two groups with respect to sex, medical illnesses, pre-operative chemotherapy, radiation, or surgery, stage of disease, or type of closure (Table IV). It was found that previous surgery correlated strongly to previous radiation ($p<0.01$) and so these two factors were combined for all further analysis.

The two groups differed with respect to age (Table IV). In both groups, 25 per cent of patients were 68 years or older. However, in the mouthwash group 50 per cent were 54 years or younger, while in the non-mouthwash group 25 per cent were 54 years or younger. Therefore, the median age of the mouthwash group was 52 years, while the median age for the non-mouthwash group was 61 years.

Similarly, the presence of dentition was not equally distributed between the two groups (Table IV). The edentulous condition was equivalent between the two groups, with 49 per cent of mouthwash patients being edentulous, compared to 51 per cent of the non-mouthwash patients. However, the mouthwash group contained 44 per cent

TABLE II

INCLUSIVE LIST OF WOUND COMPLICATIONS

Small wound complications (wounds which did not prolong hospitalization or were clearly a non-infectious complication)
Wound edge necrosis–no delay in discharge
Small area of exposed bone–no discharge delay
Wound dehiscence over mandible spacer–no discharge delay
Pectoralis myocutaneous flap dehiscence from mandible–secondary to flap's weight, not infection
Granulation tissue–no discharge delay
Chyle fistula–not an infectious complication
Large wound complications (wounds whose care prolonged hospitalization or required a second operation)
Orocutaneous fistula
Exposed bones/plating systems–needing skin graft
Exposed necrotic bone flap–needing secondary removal and closure
Wound dehiscences requiring operations to close

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TABLE III
INTER-EVALUATOR RECLASSIFICATION OF WOUND COMPLICATIONS

Description of wound	Original wound class	New wound class
Persistent tumour extruding from closure line	Large	None
Drain sucking liquid from neck–chyle fistula, not infection delaying discharge	Large	Small
Exposed bone–no delay in discharge	Large	Small
Large dehiscence needing several operations to close	Small	Large
External wound de-epithelialization – no delay in discharge	Small	None
Died post-operatively with de-epithelialization of external wound	Small	None
Pectoralis myocutaneous flap dehiscent from mandible–secondary to flap's weight, not infection	None	Small
Seroma	Small	None
Exposed bone in maxillectomy cavity	Small	None
Exposed sequestrum of anterior nasal spine	None	Small
Intra-oral closure mucosalized	Small	None
Small area of gingival 'irritation' above third molars after partial glossectomy	Small	None
Orocutaneous fistula	Small	Large
Exposed bone, needing secondary operation	Small	Large
Mandibular plate area, originally well-healed but becoming infected three months later	Large	None
Drainage from neck wound – fistula never proved but discharge delayed in treatment	Small	Large
Exposed area of bone – no delay in discharge	Large	Small
Buccal wound healed, then subsequent fistula formation after the start of radiation therapy	Large	None

with good teeth, *versus* 25 per cent with good teeth in the non-mouthwash group. In other words, only seven per cent of the mouthwash patients had poor teeth, while 24 per cent of the non-mouthwash patients had poor teeth.

Risk factors and wound outcome

Previous radiation or surgery, stage of disease, closure type, and the presence of a pre-operative mouthwash preparation correlated strongly to wound outcome (Table V). The factor of previous radiation was linked so strongly with previous surgery, that statistically they could not be separated. Both factors, taken together, correlated to worse wound outcome. More advanced stages of disease, and recurrent disease, correlated to worse wound outcome. In analysis of the type of closure, primary closure and free flap closure showed equal effects on wound outcome. Both primary closure and free flap closure correlated with better wound results than pedicled flap closure.

The presence of mouthwash preparation correlated with both less frequent, and less severe wound complications (Table VI). Of the patients in the mouthwash group 4.6 per cent showed large wound complications, compared to 31.7 per cent in the non-mouthwash group. Of those in the mouthwash group 88.4 per cent had no wound complication, compared to 61.9 per cent of those in the non-mouthwash group. The presence of the mouthwash preparation was then compared to the other three significant factors to see if it was statistically linked to any of those, and therefore was itself significant only by virtue of that association. No significant interaction was found between the presence of a preparation and the other factors (Table VII). In summary, the use of a pre-operative povidone–iodine mouthwash correlated significantly ($p<0.01$) with better wound outcome.

TABLE IV
DISTRIBUTION OF RISK FACTORS BETWEEN THE MOUTHWASH AND NON-MOUTHWASH PATIENT GROUPS (ONLY YOUNGER AGE AND BETTER TOOTH CONDITION ARE UNEVENLY DISTRIBUTED TO THE TREATMENT ARM)

Sex
15 (34.9 per cent) with mouthwash are female
25 (39.7 per cent) without mouthwash are female
Exact $p = 0.68$ (nonsignificant)

Age
Median = 52 years with mouthwash
Median = 62 years without mouthwash
Wilcoxon $p = 0.03$ (significant)

Teeth
19 (44.2 per cent) with mouthwash with good dentition
16 (25.4 per cent) without mouthwash with good dentition
Exact $p = 0.03$ (significant)

Pre-existing medical illness
7 (16.3 per cent) with mouthwash are positive
6 (9.5 per cent) without mouthwash are positive
Exact $p = 0.37$ (nonsignificant)

Pre-operative chemotherapy
2 (4.6 per cent) with mouthwash are positive
2 (3.2 per cent) without mouthwash are positive
Exact $p = 1.00$ (nonsignificant)

Pre-operative radiotherapy
17 (39.5 per cent) with mouthwash are positive
22 (34.9 per cent) without mouthwash are positive
Exact $p = 0.68$ (nonsignificant)

Previous surgery
17 (39.5 per cent) with mouthwash are positive
22 (34.9 per cent) with mouthwash are positive
Exact $p = 0.68$ (nonsignificant)

Previous radiotherapy or surgery
21 (48.4 per cent) with mouthwash are positive
29 (46.0 per cent) without mouthwash are positive
Exact $p = 0.84$ (nonsignificant)

Stage
8 (18.6 per cent) with mouthwash were non-oncological procedures
7 (11.1 per cent) without mouthwash were non-oncological procedures
Exact $p = 0.39$ (nonsignificant)

6 (13.9 per cent) with mouthwash were for stage 1 or 2 disease
17 (39.5 per cent) with mouthwash were for stage 3 or 4 disease
12 (27.9 per cent) with mouthwash were for recurrent disease
10 (15.9 per cent) without mouthwash were for stage 1 or 2 disease
31 (49.2 per cent) without mouthwash were for stage 3 or 4 disease
15 (23.8 per cent) without mouthwash were for recurrent disease
Exact $p = 0.71$ (nonsignificant)

Closure type
10 (23.3 per cent) with mouthwash were closed by free flap
21 (49.8 per cent) with mouthwash were closed primarily
12 (27.9 per cent) with mouthwash were closed with a pedicled flap
20 (31.7 per cent) without mouthwash were closed by free flap
29 (46.0 per cent) without mouthwash were closed primarily
14 (22.2 per cent) without mouthwash were closed with a pedicled flap
Exact $p = 0.60$ (nonsignificant)

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TABLE V

CORRELATION OF RISK FACTORS TO WOUND OUTCOME (PREVIOUS RADIOTHERAPY/SURGERY, STAGE, AND NO MOUTHWASH PREPARATION ARE UNEVENLY DISTRIBUTED TO THE POORER WOUND OUTCOMES)

Factor	p-value	Significance
Sex	0.40	Nonsignificant
Age in years	0.64	Nonsignificant
Dentition	0.53	Nonsignificant
Pre-existing illness	0.35	Nonsignificant
Previous radiotherapy/surgery	<0.01	Significant
Stage	<0.01	Significant
Closure	<0.01	Significant
Mouthwash preparation	<0.01	Significant

Finally, the possible interactions of the factors of age and tooth condition with the mouthwash preparation were investigated. Age in years and tooth condition had been shown to be nonsignificant to wound outcome (Table V). In addition, their interaction and possible linkage with the mouthwash preparation was found to be nonsignificant ($p = 0.47$). Thus, although the patients in the mouthwash arm of the study were younger and had better dentition than those in the control arm, the significant effect of the mouthwash preparation on wound outcome was not associated with age or tooth condition.

Second statistical analysis

The data were analysed a second time to try to eliminate all opportunities for bias. There were eight patients who underwent two operations in the cohort, and the second operation of each of these was discarded. This decision was to remove the possibility that a poor wound outcome would be perpetuated from the earlier operation into the data of the later operation. This left 98 patients.

Additional risk factors were analysed. The presence of a neck dissection was added, as was the administration of pre-operative and post-operative intravenous anti-staphylococcal and anti-anaerobic antibiotics. These additional risk factors were distributed equally to both mouthwash and control groups (Table VIII).

Finally, the risk factors were correlated against orocutaneous fistula as the end point for wound complications. It was felt that orocutaneous fistula was an unequivocal end point and that its presence or absence did not depend on clinical judgement. This manipulation was especially relevant in the context of a retrospective review of descriptions in other studies.

TABLE VI

CORRELATION OF MOUTHWASH TO THE PREVALENCE AND SEVERITY OF WOUND COMPLICATIONS (POORER WOUND OUTCOME IS UNEVENLY DISTRIBUTED TO THE NO TREATMENT ARM)

Wound outcome
2 (4.6 per cent) with mouthwash had a large wound complication
3 (7.0 per cent) with mouthwash had a small wound complication
38 (88.4 per cent) with mouthwash had no wound complication
20 (31.7 per cent) without mouthwash had a large wound complication
4 (6.3 per cent) without mouthwash had a small wound complication
39 (61.9 per cent) without mouthwash had no wound complication
Exact $p<0.01$ (significant)

Re-evaluation of all the risk factors for wound complication demonstrated no changes in the previously determined risk factors for wound infection. However, the absence of a neck dissection, and the use of anti-staphylococcal antibiotics post-operatively correlated with better wound outcome (Table IX). The odds ratio for neck dissection varied with the number of risk factors considered in the calculation. When all risk factors were considered, the odds of having a favourable wound outcome in those patients undergoing a neck dissection were one-tenth of those patients without a neck dissection. When only the significant factors were considered, the odds of having a favourable wound outcome in the neck dissection group were one quarter of those in the patients without neck dissection. Once again, the presence of a pre-operative mouthwash showed no interaction with the other significant variables.

Of the antibiotic options tested in the analysis, the presence of post-operative anti-staphylococcal antibiotics was the only significant factor. Only five of the 98 patients received no perioperative intravenous antibiotics. Further, the antibiotic combinations were closely linked, since most patients received pre-operative and post-operative cefazolin and metronidazole. However, it appeared that those patients receiving a post-operative anti-staphylococcal antibiotic were 13 times more likely to have a good wound outcome than those not receiving a post-operative anti-staphylococcal antibiotic.

The incidence of wound complication remained much lower in the mouthwash than in the control group (Table X). There were no orocutaneous fistulae in the mouthwash group, and the only 'large' wound complications had been eliminated by discarding the redundant eight patients. When all risk factors were taken together, the odds were that a mouthwash patient was 40 times more likely to have a good wound outcome than a control patient. When only the significant risk factors were included in the analysis, a mouthwash patient was 23 times more likely to have a good wound outcome.

Discussion

The risk factors for wound complications after head and neck oncological surgery have been investigated in many previous studies. In our study, the major risk factors for poor wound outcome were previous radiation or surgery, pedicled flap closure, stage of disease, neck dissection, failure to administer post-operative intravenous antibiotics, and the failure to use a pre-operative antiseptic preparation.

Pre-operative radiation therapy has been shown to

TABLE VII

STATISTICAL ANALYSIS DEMONSTRATING NO INTERACTION OF SIGNIFICANT RISK FACTORS WITH THE PRESENCE OF A MOUTHWASH PREPARATION

Previous radiotherapy/surgery
Mouthwash: $p = 1.00$ (nonsignificant)
Stage
Mouthwash: $p = 0.96$ (nonsignificant)
Closure
Mouthwash: $p = 0.96$ (nonsignificant)

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TABLE VIII

DISTRIBUTION OF ADDITIONAL SIGNIFICANT RISK FACTORS BETWEEN MOUTHWASH AND CONTROL GAPS – SECOND ANALYSIS (EVEN DISTRIBUTION OF ADDITIONAL RISK FACTORS TO BOTH ARMS OF STUDY)

Neck dissection
19 (45.7 per cent) with mouthwash are positive
34 (57.6 per cent) without mouthwash are positive
Exact p = 0.41 (nonsignificant)
Pre-operative intravenous anti-staphylococcal antibiotic
25 (64.1 per cent) with mouthwash are positive
42 (57.6 per cent) without mouthwash are positive
Exact p = 0.51 (nonsignificant)
Post-operative intravenous anti-staphylococcal antibiotic
37 (94.9 per cent) with mouthwash are positive
53 (89.8 per cent) without mouthwash are positive
Exact p = 0.47 (nonsignificant)
Pre-operative intravenous anti-anaerobic antibiotic
23 (59.0 per cent) with mouthwash are positive
37 (62.7 per cent) without mouthwash are positive
Exact p = 0.83 (nonsignificant)
Post-operative intravenous anti-anaerobic antibiotic
32 (82.0 per cent) with mouthwash are positive
51 (86.4 per cent) without mouthwash are positive
Exact p = 0.58 (nonsignificant)

increase the rate of wound complication in some studies (Becker and Parell, 1979; Mantravadi *et al.*, 1981). Other studies do not support this (Johnson *et al.*, 1984; Robbins *et al.*, 1990; Keidan and Kusiak, 1992). In our series the factors of previous radiation therapy and previous surgery interacted so strongly that they could not be teased from one another statistically. Nonetheless, our data show a strong correlation between previous irradiation/surgery and worse wound outcome ($p<0.01$).

Another risk factor that has been investigated has been the type of wound closure. Primary closure has been shown to result in better wound outcome than pedicled muscle or myocutaneous flap closure (Johnson *et al.*, 1984; Brown *et al.*, 1987; Robbins, 1990). We too found that primary closure correlated with better wound outcome than pedicled flap closure. However, free flap closure was equal to primary closure in wound outcome.

TABLE IX

CORRELATION OF RISK FACTORS WITH WOUND OUTCOME – SECOND ANALYSIS (PREVIOUS RADIOTHERAPY/SURGERY, STAGE, NECK DISSECTION, POST-OPERATIVE ANTI-STAPHYLOCOCCAL ANTIBIOTIC, AND MOUTHWASH PREPARATION ARE DISPROPORTIONATELY ASSOCIATED WITH POORER WOUND OUTCOME)

Factor	p-Value	Significance
Sex	0.71	Nonsignificant
Age	0.63	Nonsignificant
Dentition	0.77	Nonsignificant
Pre-existing illness	0.27	Nonsignificant
Previous radiotherapy/surgery	0.01	Significant
Stage	0.05	Significant
Closure	0.04	Significant
Neck dissection	0.04	Significant
Pre-operative anti-staphylococcal antibiotic	0.21	Nonsignificant
Post-operative anti-staphylococcal antibiotic	0.01	Significant
Pre-operative anti-anaerobic antibiotic	0.90	Nonsignificant
Post-operative anti-anaerobic antibiotic	0.22	Nonsignificant
Mouthwash preparation	0.01	Significant

This finding is especially interesting in light of the increased operating time needed for free flap closure. It has been demonstrated that the incidence of wound infection increases with the length of time of the operation (Davidson *et al.*, 1971; Robbins *et al.*, 1990). But in our series the wound infection rate with free flap closure, which is the slowest method of closure, was equal to that of primary closure, which is the fastest method of closure. Perhaps the favourable outcome with free flap closure is reflective of the superior blood supply, and reduced suture line tensions seen with free flap closure. Perhaps, too, those candidates who are selected for free flap over pedicled flap closure appear healthier overall from their clinical impression.

Advanced stage of disease has been shown to increase wound complication rates (Brown *et al.*, 1987; Robbins *et al.*, 1990), and this was reiterated in our study. Factors which did not appear to affect wound outcome in our study were age, sex, and the condition of the teeth. Our finding that the presence of pre-existing medical illnesses did not alter wound outcome is in contrast to other reports (Robbins *et al.*, 1990) that illness is correlated with worse wound outcome. Perhaps our roster of medical illnesses which could potentially alter wound healing was too broad, thereby obscuring those illnesses that are the most detrimental to wound healing.

Finally, in its first statistical analysis, our study has shown that the use of a pre-operative antiseptic topical preparation in operations of the oral cavity and oropharynx significantly reduces the rate of post-operative wound complications. Only 4.6 per cent of those patients receiving a pre-operative mouthwash suffered a major wound complication, such as an orocutaneous fistula. This is in contrast to the 31.7 per cent of those in the non-mouthwash arm of the study whose wounds showed major complications. In the statistical analysis, the factor of receiving a mouthwash preparation was sorted independently from the other major risk factors, demonstrating that its effect on wound outcome was not linked to the other risk factors.

The results of this study so strongly supported the use of pre-operative mouthwash to reduce wound complication, that we feared that we had somehow introduced bias. Therefore, we performed a second statistical analysis in

TABLE X

CORRELATION OF MOUTHWASH TO THE PREVALENCE AND SEVERITY OF WOUND COMPLICATIONS – SECOND ANALYSIS (POORER WOUND OUTCOMES WAS UNEVENLY DISTRIBUTED TO THE NON-MOUTHWASH GROUP)

Wound outcome
0 (0 per cent) with mouthwash had an orocutaneous fistula
0 (0 per cent) with mouthwash had a large wound complication
3 (7.7 per cent) with mouthwash had a small wound complication
36 (92.3 per cent) with mouthwash had no wound complication
13 (22.0 per cent) without mouthwash had an orocutaneous fistula
5 (8.5 per cent) without mouthwash had a large wound complication
4 (6.8 per cent) without mouthwash had a small wound complication
37 (62.7 per cent) without mouthwash had a small wound complication
Exact $p<0.01$ (significant)

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which we eliminated the second procedure in all patients who underwent a second procedure. It is possible these patients were the ones with particularly poor wounds thus requiring second operations. In addition, we included other risk factors, such as neck dissection, and the type of pre-operative and post-operative antibiotic given. Finally, although these wounds were graded without reference to mouthwash status, we eliminated the possibility of bias by evaluating all the previous data against the occurrence of an orocutaneous fistula. This was felt to be an unarguable end point in wound complication evaluation.

With these manipulations, the presence of a neck dissection was found to be a significant risk factor for wound complication. Those patients undergoing neck dissection were one quarter as likely to have a favourable wound outcome. Receiving post-operative anti-staphylococcal intravenous antibiotics reduced the risk of wound complication. Both the presence of a neck dissection, and receiving an anti-staphylococcal antibiotic were evenly distributed between the mouthwash and control group. Neither risk factor interacted with the mouthwash variable.

However, despite reducing the number of patients, adding additional risk factors, and simplifying the endpoint of wound complications, the presence of a pre-operative mouthwash correlated strongly with a better wound outcome. All 13 orocutaneous fistulae were in the control group. With the elimination of the repeatedly-operated patients, there were no large wound complications in the mouthwash group. In this series, a patient was 23 to 40 times more likely to develop a wound complication if there had been no pre-operative mouthwash ($p<0.01$).

The strengths of the present study are the sample size, the types of information gathered, the analysis and listing of wound outcome, and the statistical analysis of risk factors. Information from 106 operations and their outcome was gathered. Major risk factors (radiation/surgery, stage of disease, type of closure, neck dissection, timing and type of antibiotic) were evenly distributed between the two arms of the study. The patients in the mouthwash arm tended to be younger, and tended to have better teeth, although these factors were shown to have no effect on wound outcome. Therefore, the composition of the two arms of the study is known and also known to be statistically equivalent. The criteria for large and small wound complications are presented with examples. The results of the statistical analysis show conclusively that the use of a pre-operative antiseptic mouth preparation significantly reduces the incidence of wound complications.

The mechanism by which antiseptic mouthwash reduces the incidence of wound complications is probably through the reduction of the bacterial and fungal concentrations on the oral mucosa. Earlier studies showed that the presence of oral secretions increases post-operative infection rates (Johnson *et al.*, 1984; Becker, 1986). A linear regression analysis of 1000 patients found bacterial contamination of the wound at the time of operation to be the major risk factor in post-operative wound infection (Davidson *et al.*, 1971). Another study suggests that topical antiseptics are more efficacious than intravenous antiseptics, because the agent is delivered right to the potentially infected site, at the time of potential infection (Robinson, 1976). Therefore the povidone–iodine antiseptic preparation probably yields a better wound outcome by lowering the mucosal bacterial count and thereby reducing the amount of intra-operative wound contamination.

In addition, the selection of povidone–iodine preparation over antibiotic preparations may have contributed to the results of this study. Earlier studies have shown either no reduction in bactaeremia, or no reduction in wound complication with the use of topical antibiotic preparations, such as neomycin, erythromycin, and achromycin rather than antiseptic preparations (Huffman *et al.*, 1974; Breloff and Caffesse, 1983; Jones *et al.*, 1989). However, one study has demonstrated that povidone–iodine reduces both the concentration of the normal bacterial flora, as well as that of *Candida spp.* (Exner *et al.*, 1985). Perhaps the broader range of antimicrobial toxicity of povidone–iodine contributes to its effectiveness.

Another feature of this study, which is probably significant, is our method of applying the pre-operative mouthwash. Earlier studies (Scopp and Orvieto, 1971; Exner *et al.*, 1985; Jones *et al.*, 1989) depended on the patient's gargling with the preparation pre-operatively. In our study, the gingival sulci and oropharynx are scrubbed after the patient is asleep, with a throat gag in place, and hence independent of patient cooperation. Indeed, the studies which showed some efficacy of topical preparation either administered an antibiotic directly into the open wound (Robinson, 1976; Barton and Moir, 1983), or involved the patient's gargling pre-operatively with povidone–iodine rather than an antibiotic (Scopp and Orvieto, 1971; Exner *et al.*, 1985).

Conclusions

This study helps to clarify an issue which has remained ambiguous for many years. Previously the decision to administer a pre-operative mouthwash was dependent upon surgeon preference. We present data that indicate that a topical antiseptic preparation has a favourable effect on wound outcome. In view of the low cost and morbidity of the application of topical betadine, we suggest that this measure may be a useful addition to routine transmucosal procedures.

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