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Destruction of CIN 1 and 2 with the Semm cold coagulator: 13 years' experience with a see-and-treat policy

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ABSTRACT

Objective To assess the efficacy of the Semm Cold Coagulator (100°C) for CIN 1 and 2 applying a 'see and treat' policy.

Design Retrospective review of women with CIN 1 and 2 seen and treated at their first visit when specific criteria were satisfied.

Setting Colposcopy Clinic, Ninewells Hospital, Dundee.

Subjects 485 women with CIN 1 and 680 women with CIN 2 confirmed by colposcopically directed biopsy and treated between 1 January, 1978 and 31 December, 1990.

Results Overall, a 96·7% primary success rate with a single treatment (97·1% for CIN 1, 96·5% for CIN 2) and 99% overall success rate after one or more treatments with the cold coagulator. None of the women developed micro-invasive or invasive cancer and only 1·1% developed CIN 3. In 98·3% treatment was undertaken at their first and only colposcopy clinic attendance. Heavy vaginal bleeding occurred in 1·5% after treatment and 0·6% complained of a heavy vaginal discharge. One woman developed cervical stenosis which required dilatation because of dysmenorrhoea.

Conclusion Cold coagulation at 100°C of CIN 1 and 2 proven by colposcopically directed biopsy using a 'see and treat' policy subject to specific conditions is a safe, cost effective, practical approach. It is more likely to return the cervix to sustained normality than withholding treatment and simply maintaining cytological surveillance, and it should prevent some of the invasive cancers that have been described in reports of management by cytological surveillance.

The aim of a cervical screening programme is a reduction in deaths from cervical cancer. Achievement of this aim requires efficient detection and effective treatment of pre-malignant disease. The Guidelines for Clinical Practice and Programme Management published recently by the National Co-ordinating Network of the National Health Service Cervical Screening Programme (Duncan 1992) endorse the referral for colposcopy of women with moderate or severe dyskaryosis the first time it is seen on a smear. These guidelines also recommend referral for colposcopy of women with smears showing persistent borderline changes or mild dyskaryosis and the treatment of cervical intraepithelial neoplasia (CIN) 2 and 3. Gordon and Duncan (1991) reported effective destruction of CIN 3 with the Semm cold coagulator, justifying the 'see and treat' policy which has been in place in Ninewells Hospital, Dundee, since 1978. The referral policy outlined above was used informally for many years and has been official policy in this unit since 1987, since when 40·5% of the women referred with dyskaryotic smears have had mild dyskaryosis, 44·5% had moderate dyskaryosis and 15% had severe dyskaryosis. We treat women referred to us immediately after colposcopically directed biopsy, provided the whole of the transformation zone can be seen and there is no suspicion of micro-invasive or invasive carcinoma, or glandular abnormality. This policy leads to treatment of all grades of CIN in the same way. The outcome of management of CIN 3 by this approach has been reported by Gordon and Duncan (1991). We have examined the outcome of this policy in the management of CIN 1 and 2.

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Subjects and methods

Colposcopic examination was performed after the application of 3% acetic acid to the cervix. Between two and four punch biopsies were taken from what were considered to be the worst areas of abnormality, using either

Table 1. Completeness of follow up in 1165 women with CIN 1 or 2, treated with cold coagulation.

Time since treatment	Followed up/eligible	%
6 months	1104/1165	94·8
1 year	1095/1159	94·5
3 years	662/801	82·6
5 years	371/478	77·6
8 years	190/243	78·2
11 years	41/66	62·1

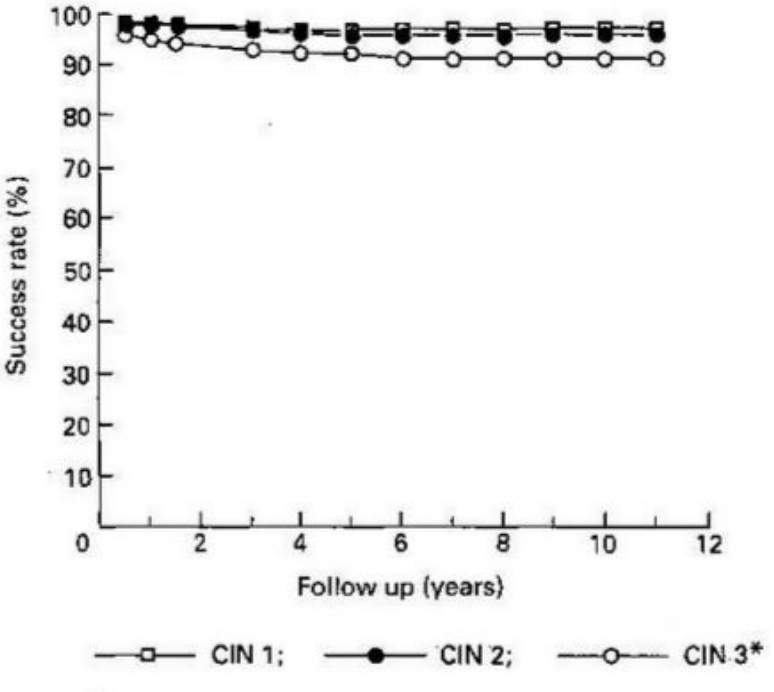
Eppendorf or Tischler-Morgan forceps. Endocervical curettage was not performed routinely and no local anaesthesia was used. When the colposcopist diagnosed abnormality no worse than CIN 3, and the whole of the transformation zone could be seen, then the whole transformation zone was destroyed by overlapping two to five areas with the thermal probe at 100°C applied for 20 s to each area. The lower endocervix was destroyed in the process. The women were advised to apply triple sulphonamide cream to the cervix with an applicator every night for a week following the treatment. They were not discouraged from using tampons and were allowed to resume intercourse as soon as they felt comfortable to so do.

The women were followed up by cytology, and colposcopy was only repeated if they had repeated borderline or mildly dyskaryotic follow up smears or a single smear showing moderate or severe dyskaryosis. Thus, the same criteria were employed for follow up colposcopy as for initial referral. The grade of CIN found in the colposcopically directed biopsies was used to determine the frequency of follow up smears. Early in the study, women with CIN 1 and 2 had smears taken four-monthly in the first year, six-monthly in the second year and then every two years until at least six years after treatment. More recently, smears have been repeated after six months and then on the first, third and fifth anniversaries of their treatment. If these were all normal, then they reverted to normal screening frequency for women of their age.

A punch card was kept separate from the case notes and used as hard copy to feed information into the On-line Cervical Cytology Update and Recall System (OCCURS) computer. This system contains details of smears taken from women not only in Tayside but also in the Fife and Central Regions of Scotland. The end points of our analysis were persistent or recurrent CIN and excision of the transformation zone by knife cone, electrosurgical loop or hysterectomy.

The records of 1204 women treated for CIN 1 and 2 from 1 January 1978 until 31 December 1990 were reviewed. None of these women had any previous history of CIN. In 39 of these women there was no record of a follow up smear and 485 women of the remaining 1165 were found to have CIN 1 and 680 had CIN 2.

Fig. 1. Actuarial primary success rate for eradication of CIN 1, 2 and 3.



*(from H.K. Gordon & I.D. Duncan 1991)

Results

The completeness of follow up ranged from 94·8% at six months through 78·2% at eight years to 62·1% at 11 years (Table 1). We considered women lost to follow up if more than six months had elapsed since their last smear was due. The greatest loss occurred between eight and 11 years. Those women who had completed 11 years of follow up had returned to routine screening frequency and were not, therefore, due to have their smear repeated on 31 December 1991 when the cytological status of all the women studied was noted.

A single treatment with the Semm cold coagulator eradicated CIN in 1127 (96·7%) of the 1165 women followed up. This overall primary success rate was essentially the same for CIN 1 (97·1%) and CIN 2 (96·5%). Figure 1 shows the primary success rate expressed in actuarial terms. For CIN 1, it fell from 98·2% after six months to 97·2% at three years and 96·5% at five, eight and 11 years. For CIN 2, the primary success rate fell from 97·6% after six months to 96·6% at three years and 95·4% at five, eight and 11 years. Of the 38 primary failures, 28 (74%) occurred within 18 months of initial treatment. Histological outcome of the failures is shown in Table 2. None of these women developed invasive carcinoma of the cervix and only 13 (1·1%) of them developed CIN 3.

The 38 failures were dealt with as follows. Twenty-six of them had repeat cold coagulation treatment. In another

Table 2. Failures of primary treatment with cold coagulation in 1165 women with CIN 1 or 2.

Diagnosis before primary treatment	Diagnosis after failed primary treatment				
	CIN 1	CIN 2	CIN 3	Invasive carcinoma	Total
CIN 1	5	4	5	0	14
CIN 2	7	9	8	0	24
Total	12	13	13	0	38

eight women, the transformation zone could not be seen in its entirety and a therapeutic cone biopsy was performed. Two women were managed by hysterectomy for coexistent dysfunctional uterine bleeding. One of these women had had four negative smears over a period of three years from her initial treatment and an unsuspected focus of CIN 2 was identified in the hysterectomy specimen at four years. One woman underwent laser ablation at another centre for CIN 3, 18 months after treatment for CIN 1. The remaining woman had CIN 2 confirmed six months after initial treatment but she declined further therapy; her follow up smears have remained negative over the three years since treatment. None of the women has had a second recurrence of CIN. The overall success rate for patients treated for CIN 1 and 2 on one or more occasions with the Semm cold coagulator is 1153/1165 (99%).

Cervical tissue was available for study in 35 women at some time after initial treatment. Thirteen women had a cone biopsy for a suspected lesion which was only confirmed in eight of them. Twenty-two women have subsequently undergone hysterectomy: a lesion was suspected in four of them, but only confirmed in one; the remaining 18 women underwent hysterectomy for other gynaecological complaints and of these only one woman, referred to above, was found to have disease in the cervix.

The 'see and treat' policy was employed in all but 20 women (1·7%) in whom the colposcopist was not satisfied with the cervical appearance and histological confirmation of CIN 1 or 2 was awaited before treatment was performed. In 1117 (96%) of the women treated, no anaesthesia was given. Most of the remainder were treated under general anaesthetic for a coincidental gynaecological condition, such as laparoscopic sterilization.

Complications

Seventeen women (1·5%) complained of heavy vaginal bleeding after the treatment and of these, four were admitted to hospital: two for dilatation and curettage, one for observation and one for blood transfusion. In the latter case, biopsy and treatment had been carried out at the same time as suction termination of pregnancy and the bleeding was from the uterine cavity, not from the treated cervix. Another woman who complained of vaginal bleeding was treated successfully as an out-patient with repeat cold coagulation.

Having been advised that they might experience vaginal discharge following treatment, seven women did report that the discharge had been heavier than anticipated. One woman developed stenosis of the cervix requiring dilatation.

It is our policy not to treat women during pregnancy and for the 22 women (1·9%) who first presented during pregnancy, colposcopy was carried out and invasive disease was excluded, but biopsy and treatment were deferred until after delivery. In another woman with irregular periods, because pregnancy was not suspected, biopsy and treatment were carried out at what was later believed to be five weeks gestation: she miscarried one week later.

The temperature of 100°C does not damage the thread of an intrauterine contraceptive device: 135 (12%) of the women were treated with an intrauterine contraceptive device in place.

Discussion

Standard practice has required that the results of colposcopically directed biopsies should be known before treatment is carried out. In this way, women with unexpected micro-invasive or invasive carcinoma or glandular abnormality would not be treated inadvertently and those with low grade lesions could be offered the option of observation rather than treatment. Contrary to convention, the 'see and treat' policy has been in operation at Ninewells Hospital since 1978 and Gordon and Duncan (1991) have previously reported that 1584 (97%) of 1628 women with CIN 3 were treated at their first visit. Thirty (2%) of these women had either micro-invasive or invasive squamous carcinoma or a glandular lesion treated inadvertently. Further investigation showed that, although undertaken inadvertently, cold coagulation had effectively destroyed the lesion in 22 of these 30 women. Residual disease was found in eight women whose management was not compromised in the longer term by their inappropriate initial treatment.

In this study, we have shown that 1145 (98·3%) of 1165 women with CIN 1 and 2 were treated at their first visit and there were no unexpected invasive, micro-invasive or glandular lesions. Excluding the women from our study who were treated in 1990, and combining our figures with those of Gordon and Duncan (1991) who reported on management of CIN 3 at the same hospital over the same time period, 2578 (97·7%) of 2640 women with CIN 1, 2 or 3 were treated at their first visit. The 'see and treat' policy applied to women with all grades of CIN over this period of time therefore led to the inadvertent treatment of malignant squamous or glandular lesions in 30 (1·1%) of 2608 women.

We are open to criticism for needlessly treating some lesions which would have regressed spontaneously but, since national guidelines (Duncan 1992) now advocate treatment of CIN 2 and 3, this criticism could only be applied to CIN 1 lesions. Campion *et al.* (1986) reviewed 10 prospective studies of mild cervical atypia in which the diagnosis of CIN 1 had been confirmed on colposcopically directed biopsy and no treatment was given. Spontaneous regression, as defined by the various authors, occurred in 26 to 83% of women in their review. Our cure rate of 97·1% for women with CIN 1, whom we followed up for up to 11 years, is clearly superior. Furthermore, of the 485 women with CIN 1 whom we treated, only five (1%) developed CIN 3.

Women with mild dyskaryosis on cervical cytology are known to have an increased risk of developing cervical cancer. Robertson *et al.* (1988) surveyed 1781 women with mild dyskaryosis, of whom 10 developed invasive cancer. In four of them, cancer was diagnosed soon after presen-

tation and, in another three, it developed some years after they had defaulted from follow up. Invasive cancer occurred in one woman during cytological surveillance and in a further two after referral for colposcopic supervision. One of the latter two women had smears showing persistent mild dyskaryosis, and a biopsy showed CIN 1; apparently she was not treated and despite further review, carcinoma was found four years later. This carcinoma might have been prevented by our method of treatment. Similarly, Fletcher *et al.* (1990) found a significantly increased incidence of invasive carcinoma of the cervix in a series of 666 women with borderline, mild or moderate dyskaryosis on routine screening. Five invasive cancers were encountered in a four and a half year follow up period, compared with less than 0·1 expected. Three of these cancers occurred in women who had persistent mild dyskaryosis following an initial mildly dyskaryotic smear. Cytological surveillance was continued, but these three invasive cancers might also have been prevented by our method of treatment.

The malignant potential of CIN 1 is not fully understood and the outcome of further studies of different management policies are awaited with interest. Both Robertson *et al.* (1988) and Fletcher *et al.* (1990) have highlighted the problem of default from follow up during surveillance. We believe that this problem is less important after treatment.

Our study demonstrates the advantages of a 'see and treat' policy for women with a single moderately or severely dyskaryotic smear, or a second borderline or mildly dyskaryotic smear, provided the whole of the transformation zone can be seen and there is no suspicion of micro-invasive or invasive squamous carcinoma or glandular lesion. This approach is safe and cost effective. It saves time, expense and unnecessary anxiety. It avoids the need for waiting lists for treatment. The dangers of 'seeing and treating' are more imagined than real and we anticipate that this policy would have prevented some of the cancers described in cytological surveillance studies.

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