Differences in late fetal death rates in association with determinants of small for gestational age fetuses: population based cohort study

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Abstract

Objective: To examine differences in late fetal death rates in association with determinants of small for gestational age fetuses.
Design: Population based cohort study.
Subjects: 1 026 249 pregnancies without congenital malformations.
Setting: Sweden 1983-92.
Main outcome measure: Late fetal death rate.
Results: Depending on underlying determinants late fetal death rates were greatly increased in extremely small for gestational age fetuses (range 16 to 45 per 1000) compared with non-small for gestational age fetuses (1.4 to 4.6). In extremely small for gestational age fetuses late fetal death rates were increased from 31 per 1000 in mothers aged less than 35 years to 45 per 1000 in older mothers, and from 22 per 1000 in women <155 cm in height to 33 per 1000 in women ≥ 175 cm tall. Late fetal death rates were also higher in extremely small for gestational age fetuses in singleton compared with twin pregnancies and in non-hypertensive pregnancies compared with pregnancies complicated by severe pre-eclampsia or other hypertensive disorders. Slightly higher late fetal death rates were observed in nulliparous compared with parous women and in non-smokers compared with smokers.
Conclusions: Although the risk of late fetal death is greatly increased in fetuses that are extremely small for gestational age the risk is strongly modified by underlying determinants—for example, there is a lower risk of late fetal death in a small for gestational age fetus if the mother is of short stature, has a twin pregnancy, or has hypertension.

Introduction

A wide range of risk factors are associated with fetuses being small for gestational age,[1] and the prognosis for such fetuses varies according to the presence of chromosomal or other congenital malformations.[2–4] In pregnancies of small for gestational age fetuses without congenital malformations it has been assumed that constitutionally small fetuses—for example, twins, or infants born to short mothers—are at lower risk of adverse outcomes than fetuses affected by other situations such as pre-eclampsia or cigarette consumption.[5 6] In fact, such an assumption underlies recent pleas for customised or individualised definitions of a fetus being small for gestational age.[7 8] Unfortunately, this assumption has rarely been critically tested.[9 10]

In Sweden the population based birth register includes information on risk factors for fetuses being small for gestational age including maternal age, height, parity, smoking habits, blood pressure status, and type of pregnancy (single or multiple). We used this information to study the differences in late fetal death rates in association with fetal size and underlying determinants of a fetus being small for gestational age.

Subjects and methods

Swedish birth register

In Sweden data from all hospital births, including demographics, reproductive history, and complications during pregnancy and delivery, are collected prospectively and recorded in a birth register.[11] From 1983 to 1992 1 083 367 births were recorded. Our study was restricted to singleton or twin pregnancies without congenital malformations, according to ICD-8 (international classification of diseases, 8th revision) and ICD-9 (9th revision) codes 740-759, in women aged 15 to 44 years (n = 1 026 249).

Maternal height and smoking habits are recorded at the time of registration for antenatal care. Parity is defined as the number of previous births, including stillbirths. Maternal age is defined as completed years at delivery. Any maternal disorders are noted by an obstetrician at the time of the woman's discharge. Hypertension is defined as[12]: essential (ICD-8 code 401 and ICD-9 codes 642A-C); gestational (non-proteinuric) (ICD-8 code 637.01 and ICD-9 codes 640D and 642X); mild (proteinuric) pre-eclampsia (ICD-8 code 637.03 and ICD-9 code 642E); severe (proteinuric) pre-eclampsia (ICD-8 code 637.04 and ICD-9 code 642F); and eclampsia (ICD-8 code 637.1 and ICD-9 code 642G). The 250 women with eclampsia were grouped with 5145 women with severe pre-eclampsia.

Birthweight ratio was defined as the ratio of observed to expected birth weight on the basis of the fetuses' gestational age and sex. Explanatory variables were the fetuses' sex, a third degree polynomial of

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Table 1 Number of births and late fetal deaths associated with maternal characteristics, type of birth, and birthweight ratio in Sweden from 1983 to1992

	No (%) of births	Late fetal death (No/1000)	Birthweight ratio (mean)
Maternal age (years):			
15-19	30 926 (3)	116 (3.8)	0.97
20-24	240 325 (23)	748 (3.1)	0.99
25-29	379 650 (37)	1180 (3.1)	1.00
30-34	257 643 (25)	845 (3.3)	1.00
35-39	100 233 (10)	460 (4.6)	1.01
40-44	17 472 (2)	90 (5.2)	1.01
Parity:			
No previous births	424 240 (41)	1598 (3.8)	0.97
One or more previous births	602 009 (59)	1841 (3.1)	1.01
Smoking (cigarettes per day):			
0	696 453 (68)	2036 (2.9)	1.01
1-9	159 643 (16)	593 (3.7)	0.97
⩾10	100 499 (10)	499 (5.0)	0.95
No data	69 654 (7)	311 (4.5)	0.99
Maternal height (cm):			
⩽154	22 768 (2)	76 (3.3)	0.94
155-174	686 356 (67)	1967 (2.9)	1.00
⩾175	58 851 (6)	149 (2.5)	1.04
No data	258 274 (25)	1247 (4.8)	1.00
Hypertensive disorders:			
None	992 831 (97)	3262 (3.3)	1.00
Gestational	20 051 (1)	42 (4.2)	0.97
Essential	1 746 (0.2)	20 (11.5)	0.94
Mild pre-eclampsia	16 186 (2)	51 (3.2)	0.96
Severe pre-eclampsia	5 435 (0.5)	64 (11.8)	0.88
Type of birth:			
Singleton	1 005 1 29 (98)	3242 (3.2)	1.00
Twin	21 120 (2)	197 (9.3)	0.88
Small for gestational age:			
None	803 274 (78)	1647 (2.1)	
Mild	196 311 (19)	917 (4.7)	
Extreme	26 664 (3)	875 (32.8)	
Total	1 026 249 (100)	3439 (3.4)	1.00

gestational age in days, and interaction between the fetuses' sex and gestational age. A normal birthweight ratio was defined as ⩾0.90 and that of mildly and extremely small for gestational age fetuses as >0.75 but <0.90 or ⩽0.75 respectively. Late fetal death was defined as a stillbirth delivered at 28 completed weeks of gestation or later. When available, ultrasonography was used to estimate gestational age during the second trimester otherwise gestational age was estimated from the last menstrual period. At the start of the study 50% of the obstetric departments performed routine ultrasonography. From 1990 onwards all pregnant women in Sweden were offered ultrasonography before 18 weeks' gestation.[13 14]

We used multiple logistic regression analyses to estimate the effect of independent variables on late fetal death.

Results

Risk factors

Late fetal death rates were increased in women who were 35 years or older, were nulliparous, smoked, or were <155 cm in height (table 1). Essential hypertension, severe pre-eclampsia, and twin pregnancies were associated with greatly increased late fetal death rates. In pregnancies of normal birthweight ratio the late fetal death rate was 2.1 per 1000 compared with 4.7 and 32.8 per 1000 in pregnancies of mildly and extremely small for gestational age fetuses respectively.

Table 1 shows the relation between maternal and fetal characteristics and birthweight ratio. Maternal smoking habits and height influenced the mean birthweight ratio in a dose dependent manner but the largest effects were observed in women with severe pre-eclampsia or twin pregnancies.

Late fetal death rates and mean birthweight ratios were similar for women aged 20-24, 25-29, and 30-34 years. Compared with severe pre-eclampsia other hypertensive disorders were either uncommon or had a comparatively small influence on late fetal death or birthweight ratio. In the logistic regression analyses maternal age was grouped as 15-19, 20-34, and 35-44 years, and hypertension as none, severe pre-eclampsia, and other hypertensive disorders. Multiple logistic regression analyses showed that there was an increased risk of late fetal death in women who were 35 years or older, were nulliparous, smoked, had twin pregnancies, or had severe pre-eclampsia (table 2).

In a second logistic model we estimated the crude effect of being small for gestational age on the risk of late fetal death. Compared with fetuses of a normal birthweight ratio the risk was doubled in fetuses mildly small for gestational age (odds ratio 2.3, 95% confidence interval 2.1 to 2.5) and greatly increased in fetuses extremely small for gestational age (16.5, 15.2 to 17.9).

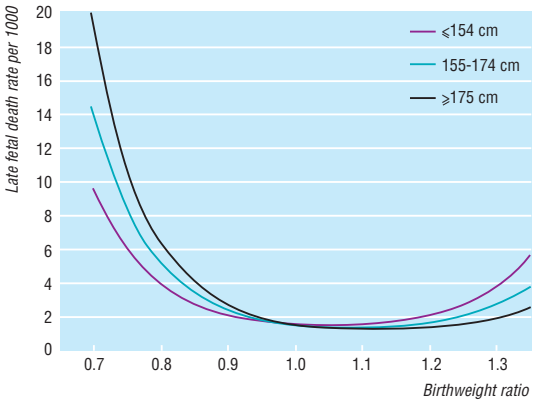
Risk factors and birthweight ratio

To determine whether the increased risk of late fetal death related to a fetus being small for gestational age was modified by underlying determinants, we introduced interaction terms in the logistic regression models. Important interaction terms were found between birthweight ratio and all determinants studied except maternal age, and predicted rates of late fetal death

Table 2 Adjusted odds ratios (95% confidence intervals) of late fetal death compared with maternal characteristics of women recorded in the Swedish birth register from 1983 to 1992

Variable	Odds ratio (95% CI)
Maternal age (years):	
15-19	1.0 (0.8 to 1.2)
20-34*	1.0
35-44	1.6 (1.4 to 1.7)
Parity:	
No previous births	1.4 (1.3 to 1.5)
One or more previous births*	1.0
Smoking (cigarettes per day):	
0*	1.0
1-9	1.3 (1.2 to 1.4)
⩾10	1.7 (1.6 to 1.9)
Maternal height (cm):	
<154	1.2 (0.9 to 1.5)
155-174*	1.0
⩾175	0.9 (0.7 to 1.0)
Hypertensive disorders:	
None*	1.0
Severe pre-eclampsia	3.1 (2.4 to 4.0)
Other	1.1 (0.9 to 1.4)
Type of birth:	
Singleton*	1.0
Twin	2.8 (2.5 to 3.3)

*Reference group.



Rates of late fetal death compared with maternal height and birthweight ratio

were calculated as a function of birthweight ratio and its determinants (table 3). In extremely small for gestational age fetuses late fetal death rates ranged from 16 to 45 per 1000, which varied according to underlying determinants. In mildly small for gestational age fetuses late fetal death rates ranged from 2.3 to 8.7 per 1000, and from 1.3 to 4.6 per 1000 in fetuses of a normal birthweight ratio.

In extremely small for gestational age fetuses the predicted late fetal death rate was 33.1 per 1000 in women aged less than 35 years *v* 44.9 per 1000 in older women. Late fetal death rates also increased with maternal height, and were higher in singletons compared with twins and in non-hypertensive pregnancies compared with pregnancies complicated by hypertensive disorders. Slightly higher late fetal death rates were also observed in nulliparous women and in non-smokers. In mildly small for gestational age fetuses late fetal death rates were increased in women who were 35 years or older, were ⩾155 cm in height, had twin pregnancies, or had severe pre-eclampsia. In fetuses of a normal birthweight ratio late fetal death rates were increased among women who were 35 years or older, were <155 cm in height, were nulliparous, smoked, had twin pregnancies, or had severe pre-eclampsia. Of the late fetal deaths, 51% were in the preterm period and 49% were at or after term. When the analyses in table 3 were restricted to full term pregnancies late fetal death rates were reduced: 0.9 per 1000 in non-small for gestational age fetuses and 2.3 and 9.8 in mildly and extremely small for gestational age fetuses respectively. The comparative increase in late fetal death rates by risk factors and birthweight ratio, however, remained unchanged (data not shown).

The impact of maternal height on late fetal death rate is shown when using birthweight ratio as a continuous variable (figure). Late fetal death rates consistently increased with decreasing birthweight ratio regardless of maternal height, but the increase was most pronounced among women ⩾175 cm in height.

Table 3 Adjusted rates and 95% confidence intervals of late fetal death compared with characteristics of pregnancy and birthweight ratio based on multiple logistic regression. Model includes significant interactions between risk factors and birthweight ratio

	Small for gestational age		
	None	Mild	Extreme
Variable	Rate/1000 (95% CI)	Rate/1000 (95% CI)	Rate/1000 (95% CI)
Maternal age (years):			
15-19	1.4 (1.1 to 1.7)	3.8 (3.1 to 4.8)	31.1 (24.9 to 38.8)
20-34*	1.4 (1.2 to 1.5)	3.8 (3.4 to 4.3)	31.1 (27.5 to 35.1)
⩾35	2.0 (1.8 to 2.2)	5.6 (4.9 to 6.4)	44.9 (39.1 to 51.4)
Parity:			
No previous births	1.6 (1.5 to 1.7)	3.6 (3.3 to 4.1)	36.7 (32.7 to 41.1)
One or more previous births*	1.4 (1.2 to 1.5)	3.8 (3.4 to 4.3)	31.1 (27.5 to 35.1)
Smoking (cigarettes per day):			
0*	1.4 (1.2 to 1.5)	3.8 (3.4 to 4.3)	31.1 (27.5 to 35.1)
1-9	1.5 (1.3 to 1.8)	3.5 (2.9 to 4.1)	26.9 (23.0 to 31.5)
⩾10	2.3 (2.0 to 2.7)	3.8 (3.1 to 4.5)	28.3 (23.8 to 33.5)
Maternal height (cm):			
⩽154	1.7 (1.1 to 2.4)	2.3 (1.4 to 3.7)	22.2 (15.3 to 32.1)
155-174*	1.4 (1.2 to 1.5)	3.8 (3.4 to 4.3)	31.1 (27.5 to 35.1)
⩾175	1.4 (1.2 to 1.7)	4.0 (3.3 to 4.9)	32.8 (26.9 to 39.9)
Type of birth:			
Singleton*	1.4 (1.2 to 1.5)	3.8 (3.4 to 4.3)	31.1 (27.5 to 35.1)
Twin	4.6 (3.6 to 6.0)	4.3 (3.2 to 5.7)	22.8 (18.1 to 28.7)
Hypertensive diseases:			
None*	1.4 (1.2 to 1.5)	3.8 (3.4 to 4.3)	31.1 (27.5 to 35.1)
Severe pre-eclampsia	3.1 (2.2 to 4.4)	8.7 (6.1 to 12.3)	21.7 (15.0 to 31.2)
Other	1.3 (1.0 to 1.6)	3.6 (2.7 to 4.6)	15.7 (11.6 to 21.3)

*Reference group.

Discussion

This study shows that late fetal death rates associated with a fetus being extremely small for gestational age are low in women who are less than 35 years, ⩽155 cm in height, have twin pregnancies, or have severe pre-eclampsia or other hypertensive disorders. Hypertensive disorders are well documented determinants of a fetus being small for gestational age, and close antenatal supervision may contribute to the favourable prognosis in these pregnancies. The reduced risks associated with short stature and multiple births, however, support the assumption that a small for gestational age fetus may be the result of constitutional rather than pathological factors.[5–8] Even in short mothers, however, late fetal death rates were more than 10-fold higher in extremely small for gestational age fetuses compared with fetuses of a normal birthweight ratio clearly indicating that even in short mothers the consequences of a fetus being small for gestational age may be serious.

In pregnancies of a normal birthweight ratio the risks of late fetal death were influenced by maternal age, smoking habits, multiple births, and severe pre-eclampsia. These factors increase the risks of severe placental complications,[15–18] which may cause fetal death without affecting the birthweight ratio.

Late fetal death rates were higher among women older than 35 years regardless of the birthweight ratio. The risk of late fetal death has been reported to increase progressively with gestational age and this increase is pronounced among women older than 35 years.[19 20] Risks of placental complications increase with maternal age, and vascular degenerative changes have been observed in the uterine and myometrial arteries of women of older childbearing age[21 22]; this suggests that late fetal death may be due to an age related effect as a consequence of uteroplacental underperfusion.

Methodological considerations

Chance is an unlikely explanation for our findings because of the large size of the study and the correspondingly narrow confidence intervals of our observed rates and odds ratios. The prospective nature of data collection precludes recall bias. As some risk factors of a fetus being small for gestational age are associated with increased risks of congenital anomalies the study was restricted to pregnancies without congenital malformations.

The conclusions from this investigation are, however, limited by the risk factors included in the birth register. We lacked information on the womens' socioeconomic position, prepregnancy body mass index, and weight gain during pregnancy, which are important determinants of birthweight ratio.[1] Socioeconomic position and prepregnancy body mass index are also associated with the risk of late fetal death.[23 24] The association between weight gain during pregnancy and late fetal death, however, is less certain.[24 25] The risks of a fetus being small for gestational age and late fetal death related to maternal age and smoking habits, however, seem to be largely independent of socioeconomic position and prepregnancy body mass index.[1 23 24 26] Maternal height was not an important factor in the overall risk of late fetal death, which agrees with a previous investigation.[24] The effect of maternal height on birthweight ratio is reported to be the same both before and after adjusting for confounders. The effect of maternal height on the risk of late fetal death associated with birthweight ratio is therefore unlikely to be due to residual confounding.[27 28]

An accurate estimation of the birthweight ratio in cases of late fetal death is limited as estimates of gestational age and fetal weight are based on time of delivery rather than time of death. This not only leads to an overestimation of gestational age but the dead fetus may also have lost weight before delivery,[29] and the birthweight ratio may therefore be underestimated in these pregnancies. The extent of this bias is, however, probably limited. Firstly, almost all pregnant women in Sweden follow the routine schedule of visiting their antenatal clinic every second week from 24 weeks' gestation and weekly from 36 weeks, and fetal heart activity is registered at each visit. Secondly, the women are routinely told to contact their antenatal clinic or obstetric department immediately if there is a decrease in fetal movements. Thirdly, the time from diagnosis of a late fetal death to delivery is generally reported as less than 24 hours.[30] These factors should ensure a comparatively short delay between the time of fetal death and the time of delivery. In a study of fetal histology and stillbirth in the United States, it was estimated that 80% of all stillbirths were delivered within one week of death.[31]

Conclusions

Highlighting the risk factors of late fetal death in small for gestational age fetuses is especially important in countries with low infant mortality rates. In the present study, in which all infants with congenital malformations were excluded, late fetal deaths accounted for more than 50% of all late fetal and infant deaths in Sweden from 1983 to 1992. This study shows that the risk of late fetal death in a small for gestational age fetus may be modified by the underlying determinants of birthweight ratio. The very strong relation between late fetal death and a small for gestational age fetus should, however, be re-emphasised; a fetus that is extremely small for gestational age is associated with a high risk of late fetal death, regardless of cause, and must therefore be monitored.

Key messages

- Small for gestational age fetuses are at increased risk of late fetal death regardless of the underlying determinants
- The effect of birthweight ratio on risk of late fetal death is modified by underlying determinants, except maternal age
- Regardless of birthweight ratio the rates of late fetal death are higher among women aged 35 years or older compared with younger women
- In pregnancies of extremely small for gestational age fetuses lower rates of late fetal death are associated with a maternal age of less than 35 years, short maternal stature, multiple births, and hypertensive disorders
- In pregnancies with non-malformed fetuses late fetal death rates are increased in smokers, in multiple births, and in women with severe pre-eclampsia.

Dr Kramer is a distinguished scientist of the Medical Research Council of Canada.

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1 Kramer S. Intrauterine growth and gestational duration determinants. *Pediatrics* 1987;80:502-11.
2 Khoury MJ, Ericson JD, Cordero JF, McCarthy BJ. Congenital malformations and intrauterine growth retardation: a population study. *Pediatrics* 1988;82:83-90.
3 Ounstedt M, Moar V, Scott A. Perinatal morbidity and mortality in small-for-dates babies: the relative contribution of some maternal factors. *Early Hum Dev* 1981;5:367-75.
4 Snijders RJM, Sherrod C, Gosden CM, Nicolaides KH. Fetal growth retardation: associated malformations and chromosomal abnormalities. *Am J Obstet Gynecol* 1993;168:547-55.
5 Heinrich UE. Intrauterine growth retardation and familial short stature. *Clin Endocrinol Metab* 1992;6:589-601.
6 Wennergren M. Antenatal screening and risk factors for intrauterine growth retardation. *Int J Tech Assess Health Care* 1992;8(suppl 1):147-51.
7 Gardosi J, Chang A, Kalyan B, Sahota D, Symonds EM. Customised antenatal growth. *Lancet* 1992;339:283-7.
8 Sanderson DA, Wilcox MA, Johnson IR. The individualised birthweight ratio: a new method of identifying intrauterine growth retardation. *Br J Obstet Gynaecol* 1994;101:310-4.
9 Kramer MS, Oliver M, McLean FH, Dougherty GE, Willis DM, Usher RH. Determinants of fetal growth and body proportionality. *Pediatrics* 1990;86:18-26.
10 Sciscione AC, Gorman R, Callan NA. Adjustment of birth weight standards for maternal and infant characteristics improves the prediction of outcome in the small-for-gestational-age infant. *Am J Obstet Gynecol* 1996;175:544-7.
11 Cnattingius S, Ericson A, Gunnarskog J, Källén B. A quality study of a medical birth registry. *Scand J Social Med* 1990;18:143-8.
12 National High Blood Pressure Education Program Working Group on high blood pressure in pregnancy. *Am J Obstet Gynecol* 1990;163:1689-712.
13 Högberg U, Larsson N. Early dating by ultrasound and perinatal outcome—a cohort study. *Acta Obstet Gynecol Scand* 1997;76:907-12.
14 Åberg A, Lindmark G. Competence and compliance in antenatal care. Experience from Sweden. *Int J Tech Assess Health Care* 1992;8(suppl 1):20-4.
15 Abdella TN, Sibai BM, Hays JM, Anderson GD. Relationship of hypertensive disease to abruptio placentae. *Obstet Gynecol* 1984;63:365-70.

16 Cnattingius S. Maternal age modifies the effect of maternal smoking on intrauterine growth retardation but not on late fetal death and placental abruption. *Am J Epidemiol* 1997;145:319-23.
17 Naeye RL. The duration of maternal cigarette smoking, fetal and placental disorders. *Early Hum Dev* 1979;3:229-37.
18 Raymond EG, Mills JL. Placental abruption. Maternal risk factors and associated fetal conditions. *Acta Obstet Gynecol Scand* 1993;72:633-9.
19 Raymond EG, Cnattingius S, Kiely JL. Effects of maternal age, parity and smoking on the risk of stillbirth. *Br J Obstet Gynaecol* 1994;101:301-6.
20 Yudkin PL, Wood L, Redman CWG. Risk of unexplained stillbirth at different gestational ages. *Lancet* 1987;i:1192-4.
21 Cnattingius S, Larsson E, Weiner E. Uterine-arterial changes with age and smoking. *Int J Feto-Maternal Med* 1990;3:15-8.
22 Naeye RL. Maternal age, obstetric complications, and the outcome of pregnancy. *Obstet Gynecol* 1983;61:210-6.
23 Cnattingius S, Bergström R, Lipworth L, Kramer MS. Prepregnancy weight and the risk of adverse pregnancy outcomes. *N Engl J Med* 1998;338:147-52.
24 Little RE, Weinberg CR. Risk factors for antepartum and intrapartum stillbirth. *Am J Epidemiol* 1993;137:1177-89.
25 Rydhström H, Tydén T, Herbst A, Ljugblad U, Walles B. No relation between maternal weight gain and stillbirth. *Acta Obstet Gynecol Scand* 1994;73:779-81.
26 Haglund B, Cnattingius S, Nordström M-L. Social differences in late fetal death and infant mortality in Sweden 1985-86. *Pediatr Perinatal Epidemiol* 1993;7:33-44.
27 Barros FC, Huttly SRA, Victora CG, Kirkwood BR, Vaughan JP. Comparison of the causes and consequences of prematurity and intrauterine growth retardation: a longitudinal study in southern Brazil. *Pediatrics* 1992;90:238-44.
28 Lang JM, Lieberman E, Cohen A. A comparision of risk factors for preterm labor and term small-for-gestational-age birth. *Epidemiology* 1996;7:369-76.
29 Alessandri LM, Stanley FJ, Garner JB, Newnham J, Walters BNJ. A case-control study of unexplained antepartum stillbirths. *Br J Obstet Gynaecol* 1992;99:711-8.
30 Rådestad I, Steineck G, Nordin C, Sjögren C. Psychological complications after stillbirth—influence of memories and immediate management: population based study. *BMJ* 1996;312:1505-8.
31 Genest DR, Williams MA, Greene MF. Estimating the time of death in stillborn fetuses: I. Histologic evaluation of fetal organs; an autopsy study of 150 stillborn. *Obstet Gynecol* 1992;80:575-84.

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Cost effectiveness of community leg ulcer clinics: randomised controlled trial

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Abstract

Objectives: To establish the relative cost effectiveness of community leg ulcer clinics that use four layer compression bandaging versus usual care provided by district nurses.
Design: Randomised controlled trial with 1 year of follow up.
Setting: Eight community based research clinics in four trusts in Trent.
Subjects: 233 patients with venous leg ulcers allocated at random to intervention (120) or control (113) group.
Interventions: Weekly treatment with four layer bandaging in a leg ulcer clinic (clinic group) or usual care at home by the district nursing service (control group).
Main outcome measures: Time to complete ulcer healing, patient health status, and recurrence of ulcers. Satisfaction with care, use of services, and personal costs were also monitored.
Results: The ulcers of patients in the clinic group tended to heal sooner than those in the control group over the whole 12 month follow up (log rank $P = 0.03$). At 12 weeks, 34% of patients in the clinic group were healed compared with 24% in the control. The crude initial healing rate of ulcers in intervention compared with control patients was 1.45 (95% confidence interval 1.04 to 2.03). No significant differences were found between the groups in health status. Mean total NHS costs were £878.06 per year for the clinic group and £859.34 for the control ($P = 0.89$).
Conclusions: Community based leg ulcer clinics with trained nurses using four layer bandaging is more effective than traditional home based treatment. This benefit is achieved at a small additional cost and could be delivered at reduced cost if certain service configurations were used.

Introduction

Complete healing of venous leg ulcers can take years and recurrence is a problem.[1] Patients experience pain, affecting sleep, mobility, and quality of life.[2–4] The financial cost of venous disease in Britain has been estimated at between £294m and £650m a year.[5 6] Most care for people with leg ulcers has been provided by community nurses,[7] who use numerous treatments, although adequate information about their effect on complete healing or quality of life is not available.[6 8]

A unique graduated four layer compression bandaging system was pioneered at Charing Cross Hospital[9] and clinics in Riverside that used this system achieved a healing rate of 69% of venous ulcers in 12 weeks.[10] Estimates indicated that costs for clinics were lower than for the previous care system.[11] The effectiveness, however, remained uncertain, and concern was expressed that this uncontrolled study provided the basis for the introduction of a new leg ulcer service.[12]

A randomised controlled trial was undertaken to compare the effect of four layer bandaging in a clinic setting on healing of venous leg ulcers and health status against the usual home based care provided by district nursing services. The relative cost effectiveness of the two interventions was also evaluated.

Patients and methods

Recruitment

The study was approved by appropriate ethics committees. Recruitment was from September 1994 to May 1995 in eight clinics (four urban, two suburban, two semirural) in four community trusts in Trent. The

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