PERGAMON

European Journal of Cancer 37 (2001) 884–891

European Journal of Cancer

www.ejconline.com

Quality control of radical prostatectomy: a feasibility study

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Received 24 July 2000; received in revised form 21 November 2000; accepted 24 January 2001

Abstract

The aim of this study was to assess whether the quality of the surgical act could be an important prognostic factor for patients undergoing radical prostatectomy. This study also aims to investigate whether the surgical quality can be assessed by any means. Questionnaires were collected from 23 different institutes including 232 radical prostatectomies (RPr) performed for T1T2 prostate cancer. Blood loss, duration of surgery, margin status, postoperative prostate specific antigen (PSA) and urinary incontinence were analysed and correlated with the yearly number of RPr performed. The mean values obtained for each parameter were very different in the various centres. The outcome in terms of tumour control and incontinence could not be related to a higher or lower number of RPr performed. Quality control of RPr is feasible on the basis of an analysis of a few parameters, such as surgical margins, postoperative PSA and incontinence, that might recognise urologists that perform better or poorer than a proposed average.

Keywords: Quality control; Surgery; Prostate cancer; Radical prostatectomy; Complications

1. Introduction

Prostate cancer is becoming the commonest malignancy in men and radical prostatectomy (RPr) represents the most common form of treatment for early stage disease [1].

Indeed, RPr is a widely applied and effective treatment for localised prostate cancer. The procedure is considered as technically challenging with an intraoperative risk of bleeding and a postoperative risk of incontinence. Moreover, failure to perform a radical resection can result in positive surgical margins and the patient can show prostate specific antigen (PSA) persistence after surgery or PSA relapse during follow-up. Intra- and postoperative complications can have relevant economical implications and cancer control failure can necessitate costly adjuvant treatments such as hormonal manipulation or radiotherapy.

The number of RPr performed is still increasing and the procedure is performed by many urologists [2]. The complication rate of the procedure is quite different in different centres [3]. The quality of the surgeon and the surgery should be optimal and this study is an attempt to check whether this can be assessed by standardised means in different centres.

2. Patients and methods

A number of urological centres belonging to the Genito-Urinary (GU) Group of the European Organisation for Research and Treatment of Cancer (EORTC) that contributed significantly to a randomised EORTC protocol were asked to participate in this survey. They

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0959-8049/01/$ - see front matter
PII: S0959-8049(01)00056-9

all randomised a considerable number of patients in a joint Radiotherapy–GU protocol no. 22911, in which patients with pathological extracapsular extension or positive surgical margins were randomised after RPr to adjuvant radiotherapy or no adjuvant treatment [4].

First of all, the number of RPr carried out by each participant per year was recorded. Then a specific questionnaire on 10 retropubic RPr for clinical T1–T2 prostate cancer (5 retrospective and 5 prospective consecutive cases) had to be filled out. The following parameters were recorded: bleeding, duration of surgery, pathological margin status, serum PSA level at 3 months, incontinence status at catheter withdrawal and after 3 months.

The blood transfusion requirements correspond to the number of units of blood that were given to the patient in the perioperative period.

The duration of surgery was defined as the time between skin incision and skin closure. All centres performed a lymphadenectomy. Most of them just proceeded with the surgery without frozen section. In those centres performing frozen section, the average time waiting for the pathological result was deducted from the total operative duration.

The margin status was considered negative when the tumour was covered by healthy tissue and when the tumour did not reach the inked surface, relying on the local pathological report. When the margin was described as dubious it was considered positive.

The serum PSA level at 3 months was below or above the detection level (in order to circumvent the problem of different PSA assays).

Incontinence was recorded with observation of a 24-h pad test at catheter withdrawal at 24 h after surgery and once more at 3 months.

The results reported were recoded to highlight extremes, a score 0 meaning good, score 1 meaning fair and score 2 being poor (Table 1).

In order to be able to score the quality of a given urologist, we used an arbitrarily chosen scoring system. For items on a three-point scale (surgical and urological results) a score $++$ was assigned when $\geqslant 80\%$ of patients and a score $+$ when $>60\%$ of patients had good results. A score 0 was given when $\leqslant 60\%$ of patients had good, but $\leqslant 30\%$ had bad results and a score $-$ when $>40\%$ of patients and $--$ when $>65\%$ of patients had bad results. For items on a two-point scale (oncological results), a score $+$ was assigned when $\geqslant 80\%$ of patients had good results, a score 0 when $<80\%$ of patients had good results and $\leqslant 30\%$ bad results and a score $-$ when $>30\%$ of patients had bad results. In this scoring system, a participant quoted $++$ was considered very good, $+$ was good, 0 was fair, $-$ was poor and $--$ was very poor, for every specific parameter.

Finally, the different parameters analysed were related to the yearly number of RPr performed. These were classified in five categories: >50 prostatectomies per year, 25–50, 12–24, 5–11 and <5 per year.

Table 1
Recoding to highlight extremes: 0 = good, 1 = fair, 2 = poor

Surgical result	
Blood transfusion	0 = none, 1 = 1–3 units, 2 = > 3 units
Duration	0 = ⩽1 h 30 min, 1 = 1 h 31 min–3 h, 2 = > 3
Oncological result	
Margin status	0 = negative, 2 = positive
Prostate specific antigen (PSA) at 3 months	0 = below detection level, 2 = equal and above detection level
Urological result	
Incontinence first day	0 = none–drops, 1 = up to 2 pads, 2 = > 2 pads/total
Incontinence at 3 months	0 = none, 1 = drops, 2 = requiring the use of pads/total

3. Results

Twenty-seven urologists from 23 institutions participated and the files of 232 evaluable patients were analysed. Some urologists only sent in five forms, while others included patients with clinical T3, with prolonged previous hormone treatment or undergoing salvage prostatectomy after radiotherapy. These were excluded from the analysis as well as those that had previous transurethral resection of the prostate (TURP) (T1a–T1b). All data were collected through the local study nurse who handed over all blinded data to the EORTC GU Group statistician.

The yearly number of RPr performed per participant is quite variable. Seventy per cent of the participants ($n = 19$) did at least one RPr per month, but three participants only did between one and four.

3.1. Initial clinical and pathological stage and PSA (Table 2).

The preoperative clinical stage was cT1c or cT2 for all patients included, but the distribution in the different centres was variable. Some institutes included only T1 (XIII) and others no T1, but only T2 tumours (IV, VIII, XVII, XVIII and XX). The definitive pathological stage determined on the RPr specimen similarly showed that some urologists had a majority of organ-confined cancers, while others had a significant incidence of extracapsular extension. Two centres reported on pT0 patients (X and XXIII), both after a 3-month course of neoadjuvant hormonal treatment. Patients with higher pathological stage (pT3–4) were seen more often by participants doing larger numbers of radical prostatectomies per year (53% of pT3–4 if more than 50 per year, 33% if 5–50 and 23% if less than 5 per year). Some

centres had no patients with an initial PSA $\leqslant$4 ng/ml (I, VIII, XV, XXIII and XXVII), while others had a significant number of patients with a PSA above 20 ng/ml (XII, XVIII, XXIV and XXV).

3.2. Surgical, oncological and urological results (Table 3).

Remarkably, the majority of urologists transfused every patient, some of them with patients who often needed more than 4 units (V and XV), while others never gave any transfusion (VII, XI and XVIII). The same holds for the duration of surgery. For most surgeons, a RPr took between 1 h 31 min and 3 h while, for some, most of the procedures took more than 3 h (II, IV, VIII, XIII and XIX). Few urologists were able to perform the surgery in less than 90 min (XII in 4/10 patients, XXIII in 4/8 patients, XXIV in 1/10 and XXVII in 1/9). In addition, the margin status was very different. Some urologists had negative margins in approximately 90% or more of radical prostatectomies (I, III, VIII, X, XIX, XXI and XXVII) and others had positive margins in more than 60% of the patients (VII, XV, XVI and XXVI), one centre even reaching 87% of margin positivity (VII). Some urologists had 90% of PSA persistence or relapse at 3 months (XVIII and XXIV), while many achieved more than 80% or more of PSA-free patients (II, III, IV, V, VIII, X, XI, XII, XVI and XXI). The continence at 24 h was assessed and showed highly variable outcomes. The degree of incontinence at 3 months was more uniformly distributed, although some urologists had 50% or more of severely incontinent patients (II, III, VII and XVI), while in others invalidating and pads requiring incontinence ($\geqslant$3 pad) was 10% or less (IX, XII, XIII and XVIII) or even non-existent (X and XVII).

A final summary of the quality survey is given in an overview (Table 4) where for the different participants the number of patients analysed, the number of radical prostatectomies performed per year are given and the quality performance concerning the different parameters is rated as proposed in the Patients and methods section.

Table 2
Summary of the clinical stage, pathological stage and the initial PSA in 232 patients undergoing RPr by 27 different urologists

Participant	Initial cT		pT				Initial PSA (ng/ml)		
	cT1c (%)	cT2 (%)	pT0 (%)	pT2 (%)	pT3 (%)	pT4 (%)	0–4 (%)	5–20 (%)	>20 (%)
I	30	70	0	80	20	0	0	80	20
II	57	43	0	29	43	28	14	86	0
III	60	40	0	90	0	10	40	60	0
IV	0	100	0	20	60	20	40	60	0
V	60	40	0	80	20	0	25	62	13
VI	45	55	0	91	9	0	18	73	9
VII	25	75	0	63	37	0	25	75	0
VIII	0	100	0	80	20	0	0	100	0
IX	70	30	0	60	30	10	20	80	0
X	30	70	20	70	10	0	40	50	10
XI	30	70	0	50	50	0	40	60	0
XII	30	70	0	40	50	10	30	40	30
XIII	100	0	0	60	40	0	20	80	0
XIV	56	44	0	44	56	0	11	89	0
XV	44	56	0	56	44	0	0	89	11
XVI	17	83	0	50	50	0	66	17	17
XVII	0	100	0	100	0	0	40	40	20
XVIII	0	100	0	30	40	30	10	60	30
XIX	60	40	0	80	20	0	20	60	20
XX	0	100	0	63	37	0	12	63	25
XXI	80	20	0	50	50	0	60	40	0
XXII	50	50	0	40	60	0	20	70	10
XXIII	50	50	13	37	50	0	0	100	0
XXIV	50	50	0	70	30	0	20	50	30
XXV	33	67	0	50	50	0	17	50	33
XXVI	17	83	0	67	33	0	17	83	0
XXVII	44	56	0	89	11	0	0	100	0

PSA, prostate specific antigen.

3.3. Correlation with the number of radical RPr

In order to find an explanation for the variability of the quality for the different parameters, the findings were correlated with the yearly number of RPr performed. The blood transfusion need was obviously higher in centres that performed fewer prostatectomies: 52% required more than 3 units if less than five RPr per year versus 0% if more than 50 RPr per year were performed. The duration of surgery was generally lower in the middle groups performing between five and 24 RPr per year than in any other group. Those who performed less than five RPr per year needed more than 3 h in nearly 40% of the procedures. The margin status and the PSA-free 3-month follow-up were remarkably comparable for all groups without any significant positive or negative correlation with the number of RPr done. While the incontinence percentages were rather inconsistent at catheter withdrawal, the degree of incontinence at 3 months proved comparable for all groups.

4. Discussion

Quality of surgery is a very controversial issue and no studies are actually reporting on the standard of surgical quality in the treatment of cancer. Radiotherapists have preceded the surgeons by approximately 30 years when they progressively developed detailed technical guidelines for radiation treatment [5]. Numerous trials are carried out on the value of adjunctive treatments to surgery, such as radiotherapy or systemic therapy, while neglecting the important function of the surgeon and surgical procedure as a prognostic factor [6].

For RPr, as for any other cancer, survival and local control are the treatment endpoints. Prostate cancer,

Table 3
Summary of the surgical, the oncological and urological results of RPr in 232 patients operated by 27 different urologists

Participants	Surgical result						Oncological result				Urological result					
	Blood transfusion			Duration			Margins		PSA		Incontinence at catheter removal			Incontinence at 3 months		
	None (%)	1–3 U (%)	⩾3U (%)	⩽1 h 30 min (%)	1 h 31–3 h (%)	>3 h (%)	Negative (%)	Positive (%)	<DL (%)	⩾DL (%)	None/drops (%)	⩽2 pads (%)	⩾3 pads (%)	None (%)	Drops (%)	⩾1 pad (%)
I	0	70	30	0	100	0	90	10	40	60	40	40	20	50	20	30
II	29	71	0	0	29	71	57	43	86	14	14	43	43	14	0	86
III	70	20	10	0	70	30	90	10	100	0	20	20	60	30	20	50
IV	20	60	20	0	40	60	40	60	80	20	40	0	60	40	20	40
V	0	10	90	0	60	40	80	20	80	20	60	30	10	60	0	40
VI	0	82	18	0	100	0	64	36	45	55	9	91	0	27	55	18
VII	100	0	0	0	100	0	13	87	25	75	50	50	0	37	13	50
VIII	90	10	0	0	40	60	90	10	80	20	10	80	10	20	60	20
IX	10	70	20	0	100	0	80	20	70	30	100	0	0	70	20	10
X	0	100	0	0	90	10	100	0	80	20	70	30	0	70	30	0
XI	100	0	0	0	90	10	70	30	80	20	50	20	30	50	30	20
XII	10	90	0	40	60	0	60	40	80	20	70	20	10	70	20	10
XIII	0	60	40	0	20	80	60	40	50	50	90	10	0	90	0	10
XIV	11	56	33	0	100	0	56	44	78	22	67	22	11	56	33	11
XV	0	22	78	0	44	56	33	67	67	33	89	11	0	56	33	11
XVI	50	17	33	0	83	17	33	67	83	17	17	17	66	17	33	50
XVII	0	40	60	0	80	20	80	20	40	60	100	0	0	80	20	0
XVIII	100	0	0	0	70	30	70	30	10	90	80	20	0	60	30	10
XIX	0	60	40	0	40	60	100	0	40	60	0	100	0	40	20	40
XX	38	62	0	0	100	0	50	50	75	25	37	13	50	50	13	37
XXI	30	70	0	0	100	0	90	10	90	10	0	30	70	70	10	20
XXII	20	70	10	0	100	0	50	50	40	60	10	70	20	50	20	30
XXIII	38	62	0	50	50	0	63	37	50	50	17	83	0	83	0	17
XXIV	50	50	0	10	90	0	60	40	10	90	20	70	10	70	0	30
XXV	67	33	0	0	100	0	67	33	50	50	0	100	0	50	17	33
XXVI	33	67	0	0	83	17	33	67	67	33	0	83	17	83	0	17
XXVII	56	33	11	11	89	0	89	11	67	33	0	75	25	50	25	25

PSA, prostate specific antigen; DL, detection level.

Table 4
Quality performance of the 27 different participants with respect to the different parameters analysed

Participants	No.	No. of RPr/year	Blood transfusion	Duration	Margin status	PSA at 3 months	Incontinence at 24 h	Incontinence at 3 months
I	10	12–24	−	0	+	−	0	−
II	7	> 50	0	−−	−	+	−	−−
III	10	25–50	+	−	+	+	−	−
IV	5	12–24	0	−	−	+	−	−
V	10	< 5	−	−	+	+	+	−
VI	11	12–24	0	0	−	−	0	0
VII	8	12–24	++	0	−	−	0	−
VIII	10	25–50	++	−	+	+	0	0
IX	10	12–24	0	0	+	−	++	+
X	10	25–50	0	0	+	+	+	+
XI	10	> 50	++	0	−	+	−	0
XII	10	12–24	0	0	−	+	+	+
XIII	10	25–50	−	−−	−	−	++	++
XIV	9	25–50	−	0	−	0	+	0
XV	9	25–50	−−	−	−	−	++	0
XVI	6	5–11	−	0	−	+	−−	−
XVII	5	5–11	−	0	+	−	++	++
XVIII	10	> 50	++	−	−	−	++	+
XIX	5	< 5	−	−	+	−	0	−
XX	8	25–50	0	0	−	0	−	−
XXI	10	> 50	0	0	+	+	−−	+
XXII	10	25–50	0	0	−	−	0	−
XXIII	8	5–11	0	0	−	−	0	++
XXIV	10	> 50	0	0	−	−	0	−
XXV	6	5–11	+	0	−	−	0	−
XXVI	6	< 5	0	0	−	−	0	++
XXVII	9	5–11	0	0	+	−	0	0

PSA, prostate specific antigen.

however, is not killing the majority of patients who have the disease. Therefore, its surgical treatment should be feasible with a low complication rate. Complications or consequences of RPr are intraoperative blood loss, postoperative incontinence and erectile impotence. The studies addressing the risk factors for postoperative complications of RPr or prospectively assessing the morbidity are scarce [7,8].

The urological centres that have participated in this survey have cooperated voluntarily. There is no doubt that the questionnaires reflect the reality, but it is impossible to rule out any selection by the participant who had to choose five retrospective cases.

The blood loss was analysed by the blood transfusion need. The transfusion need is not an ideal parameter to assess the quality of surgery. Some urologists and/or anaesthesiologists are used to replacing any blood loss, while others give transfusions only for a haemoglobin level below 100 g/l. Anyway urologists that perform fewer radical prostatectomies tend to have more significant haemorrhage. A study from the New York State Medicare Assistance of RPr revealed a mean blood loss of 1.343 ml and a median of 1.100 ml. Intraoperative transfusion was given in 75% of the operations with a mean volume of 2.5 units. In 24%, a mean volume of 1.9 units was transfused after surgery [9]. From our survey, a 'standard' RPr should need less than 1–3 units of blood transfusion, which compares well with the American data. It is, however, clear that the mean blood loss can be much less or even negligible in the hands of a particular urologist.

The duration of surgery is not a good parameter to assess the quality of an operation. In major training centres, teaching and part of the surgery being performed by the residents can be responsible for prolongation of the procedure. It could, however, be financially relevant when some urological surgeons need 3 times more theatre time for the same operation compared with others. There is actually no literature on how long a RPr should take. From this analysis, it seems feasible in less than 1 h 30 min, but mostly it takes between 1 h 31 min and 3 h. Urologists with a large case load are not always faster and there has been no relationship between the duration and any other parameter such as haemorrhage, margin status, PSA level or incontinence.

In order to evaluate the oncological result, we analysed the surgical margin status and the 3-month postoperative PSA level, although only cancer-specific and overall survival should be the endpoints to assess this

issue [10]. For T1T2 prostate cancer, the assessment of the surgical margin status could, however, be a reliable parameter to evaluate the quality of the RPr. The relevance of margin positivity is well acknowledged since it is correlated with survival. Achieving negative margins is an important prognostic parameter since the 5-year disease-free survival is significantly related to the margin status [11].

It has been well demonstrated that T1 and more specifically T1c prostate cancer is often not localised [12] and that in T2 prostate cancer understaging can be as high as 50–60% [13]. Even in the best urological departments, positive margin rates are obtained which would be unacceptable in any other tumour type.

Margin positivity is not always easy to recognise and false-positive or negative margins can be misinterpreted. For this survey central pathology was not performed; rather, the study relied on the local pathology and this can be responsible for diverging incidences of positive margins. Moreover, some patients might have had neoadjuvant hormonal treatment that could have an impact on the occurrence of positive surgical margins in cT1T2 prostate cancer.[14].

The variability that was noticed in our survey is not surprising: a review in seven different centres of 6641 patients showed a margin positivity rate varying between 14 and 41% [13]. In recent series, less positive margins are obtained because of stage migration; T1c cancer is becoming the main indication for RPr, while the number of patients with palpable disease is dramatically decreasing.

There could be a correlation between higher rates of positive surgical margins and higher preoperative PSA or higher tumour stage. Due to the small numbers of patients, this issue could not be analysed for every participant.

From recent literature and our own survey, it seems that for the actually operated T1T2 prostate cancer patients, positive surgical margins should not be accepted in more than 25%. Very experienced urological surgeons will reach 10% or less of margin positivity [13]. It is not clear why the margin status is comparable for all participants without any correlation with the number of RPr done. This confirms an earlier report showing that the outcome in a smaller clinic was similar to that from larger clinics with more experience [15]. Therefore, although often stated, a higher number of operations performed cannot be considered as a guarantee for better cancer surgery.

The same holds for the PSA-free status at 3 months. The PSA level at 3 months is not optimal to assess the successful local control since PSA persistence or PSA recurrence shortly after surgery often means systemic disease and can therefore be completely independent of the quality of the surgery. It is nevertheless obvious that only a certain percentage of PSA persistence or recurrence is acceptable after RPr for T1T2 prostate cancer [16]. Our survey shows that the majority have 80% or more patients with undetectable PSA at 3 months. Nevertheless, there is an enormous variation between the participating urologists and, for some, concern about the surgical quality could be raised. Again, this was not related to the number of surgeries performed, but probably to the individual surgical skill.

Urinary incontinence after RPr for T1T2 prostate cancer is a serious side-effect that affects quality of life. Even when the procedure is done by experienced urologists, incontinence occurs in a small minority of patients. The urinary incontinence is invariably due to damage to the striated urethral sphincter at the time of surgery [17,18]. It is clear that the surgeon's experience can influence long-term continence rates.

The incidence of incontinence is higher in patient-reported than in physician-recorded outcome analyses [17]. Therefore, again incontinence recorded by the urologist and collected through the questionnaire is far from being the optimal reflection of what is really happening. The risk factors for incontinence after RPr performed by a large group of urologists in a community setting were studied in 467 patients from 22 urologists. Complete continence was obtained in only 37% of patients and the surgeon's experience, estimated by the number of cases performed, was not a factor significantly related to continence or incontinence [19].

The patients analysed in this study are more than 50% completely dry at 3 months, while others continue to have pads for incontinence at this stage, but patients can continue to recover up to 1 year after surgery. Maybe some urologists do and others do not prescribe early pelvic floor exercises that significantly reduce the time to continence after RPr [20].

Although this study has many drawbacks and might not conclude that one participant is really doing better RPr than another, we have been able to show that, with the analysis of just a few parameters, a difference in surgical quality can be found. In the future, health insurance companies will come up with what they judge to be acceptable standards for the treatment cost of localised prostate cancer including blood transfusion and incontinence appliances, as well as adjuvant radiation or hormonal treatment. However, it is mandatory for the urological community to set its own standards for good surgical practice.

In large population centres where a few surgeons are specialising in RPr, only a few patients are referred by other urologists for surgery, while a better quality in highly specialised hands might be anticipated [15]. The number of RPr performed per year does in itself not correlate with any better or poorer results in terms of the parameters analysed. A population-based study on the hospital volume of RPr showed a significantly

higher re-admission rate and a higher risk of serious complications in the low volume institutes [21]. However, this study did not assess the surgeon volume [22] and it is clear that a meticulous and skilled surgeon can do one RPr every 3 months taking more than 3 h, without significant blood loss, with acceptable incontinence rates and perfect local tumour control. We believe that with a correct simple retrospective analysis of 10 consecutive cases done by one urological surgeon, one is able to distinguish whether the quality is good, fair or poor for each of the points of interest assessed. Considering the oncological outcome and urinary continence as a quality parameter, participant X is probably the best and participants VII, XXII, XXIV and XXV the worst performers of RPr.

Although it is risky to make any definitive statement on what 'standard radical retropubic prostatectomy' means, we could propose the following. The analysis of 10 consecutive radical prostatectomies for T1T2 prostate cancer should reveal a mean blood transfusion need of $\leqslant 3$ units, a mean operative time of less than 3 h, the mean occurrence of positive surgical margins in less than 20%, a PSA below detection level at 3 months in more than 80% and complete urinary continence at 3 months in 50% or more. It is, however, important that the data collected are assessed in a prospective manner. The standards proposed will need further validation through a more extensive and better controlled surgical quality survey. The results of such further research may nowadays become increasingly important where competition is ongoing between different management strategies for localised prostate cancer, such as retropubic or perineal open surgery, laparoscopic surgery or external beam or interstitial radiotherapy. Finally, it may be useful to indicate the minimal surgical quality requirements to centres that participate in clinical trials where surgery plays an important role.

5. Conclusions

This study is a first attempt to evaluate the quality of the surgical acts in patients undergoing RPr for clinically localised prostate cancer. The duration of surgery and the urinary incontinence at catheter withdrawal probably do not reflect the quality of the procedure, but the average blood transfusion need, the percentage of positive surgical margins, the percentage of PSA persistence or recurrence and the average incontinence after 3 months can be used to evaluate this quality. All these parameters can be, even retrospectively, analysed. The number of radical RPr performed per year is in itself not related to quality. The criteria of what a 'standard retropubic radical prostatectomy' should be, needs further validation through prospective multicentre clinical research.

Acknowledgements

We particularly acknowledge all participants and centres for their willingness to contribute to this survey: Amsterdam (D. Newling), Bern (U. Studer), Bristol (R. Persad), Brussels (P. Van Cangh), Den Bosch (A. Van der Meijden, W. Hoekstra), Hasselt (C. Vekemans), Istanbul (A. Akdas), Izmir (Z. Kirkali), Leuven (L. Baert, H. Van Poppel), Linz (W. Loidl), Lyon (J.M. Maréchal), Milan (F. Catanzaro), Newcastle (F. Hamdy), Nijmegen (G. Oosterhof), Oostende (J. Casselman), Palermo (M. Pavone-Macaluso), Rome (V. Pansadoro), Rotterdam (J. Blom), Rotterdam (W. Kirkels, G. Mickisch, F. Schröder), Stockholm (P. Hedlund), Toulouse (J.P. Sarramon), Varese (A. Bono), Vienna (W. Hoeltl).

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