

Original article

Factors associated with blood loss during radical prostatectomy for localized prostate cancer in the prostate-specific antigen (PSA)-era: an overview of the department of defense (DOD) Center for Prostate Disease Research (CPDR) National Database

Judd W. Moul<sup>a,b,\*</sup>, Leon Sun<sup>b</sup>, Hongyu Wu<sup>b</sup>, David G. McLeod<sup>a,b</sup>, Christopher Amling<sup>b,c</sup>, Raymond Lance<sup>b,d</sup>, John Foley<sup>b,e</sup>, Wade Sexton<sup>b,f</sup>, Leo Kusuda<sup>b,g</sup>, Andrew Chung<sup>b,h</sup>, Douglas Soderdahl<sup>b,i</sup>, Timothy Donahue<sup>b,j</sup>

<sup>a</sup> Urology Service, Department of Surgery, Walter Reed Army Medical Center, Washington, DC 20307-5001, USA

<sup>b</sup> Center for Prostate Disease Research (CPDR), Department of Surgery, Uniformed Services University of the Health Sciences, Bethesda, MD 20814, USA

<sup>c</sup> Department of Urology, San Diego Naval Medical Center, San Diego, CA, USA

<sup>d</sup> Urology Service, Department of Surgery, Madigan Army Medical Center, Tacoma, WA, USA

<sup>e</sup> Urology Service, Department of Surgery, Brooke Army Medical Center, San Antonio, TX, USA

<sup>f</sup> Department of Urology, Wilford Hall AF Medical Center, Lackland AFB, TX, USA

<sup>g</sup> Department of Urology, Portsmouth Naval Medical Center, Portsmouth, VA, USA

<sup>h</sup> Department of Urology, Malcolm Grow AF Medical Center, Andrews AFB, MD, USA

<sup>i</sup> Urology Service, Department of Surgery, Eisenhower Army Medical Center, Augusta, GA, USA

<sup>j</sup> Department of Urology, National Naval Medical Center, Bethesda, MD, USA

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**Abstract**

Radical Prostatectomy (RP) has been traditionally associated with significant operative blood loss and high risk of transfusion. However, over the last few years, centers of excellence have reported less bleeding and transfusion. To verify and document changes in the epidemiology of bleeding and transfusion of men electing RP, we undertook an analysis of such cases in the Department of Defense (DoD) Center for Prostate Disease Research (CPDR) Multicenter Research Database. Using the Department of Defense Center for Prostate Disease Research (CPDR) Multicenter National Research Database, a query of all RPs performed between January 1, 1985 and December 31, 2000 was conducted revealing 2918 cases with blood-loss data available for analysis from nine hospital sites. These cases were analyzed over time (calendar year) and changes in the characteristics of the patients, disease severity, and surgical results were compared with estimated blood loss (EBL) and transfusion data. Among the 2918 evaluable men, 2399 (82%) underwent a retropubic RP, 97% had clinical T1-2 disease, and 77% had a PSA level  $\leq 10.0$  ng/mL. Overall median operation time was 3.8 h, and EBL was 1000 cc. Examining trends over time, there was a dramatic decline in median operative time, EBL, and transfusion rate. In multiple linear regression analysis, operative time, operative approach, surgery year, lymphadenectomy status, and neoadjuvant hormonal therapy were significant predictor of EBL. Blood loss difference between retropubic and perineal RP became insignificant in the latter years. Radical prostatectomy is being performed more commonly on men with earlier stage disease in the PSA-Era. The operation is now performed more rapidly with less blood loss and fewer transfusion requirements. In a broad practice experience represented here, autologous blood donation would appear to be unnecessary for the majority of men and the blood loss advantage traditionally associated with perineal RP is no longer evident. © 2003 Elsevier Inc. All rights reserved.

**Keywords:** Prostate cancer; Radical prostatectomy; Blood; Transfusion

**1. Introduction**

Prostate cancer is the most common solid tumor in United States males and is the second leading cause of

cancer death [1]. Since the introduction of the prostate-specific antigen (PSA) screening test in the late 1980s and increased public awareness of the disease that occurred in the early 1990s, there has been a marked stage migration to a preponderance of clinically localized disease [2–4]. Over two-thirds of men now have localized disease at initial diagnosis and are candidates for primary local therapy with

\* Corresponding author. Tel.: +1-240-453-8951; fax: +1-240-453-8912.  
E-mail address: JMOUL@CPDR.ORG (J.W. Moul).

Table 1  
Participating CPDR sites, total prostate cancer and total radical prostatectomy cases in the database between 1985 and 2000

Abbreviation	Full name	Total CaP cases	RP cases for this study	% of RP/total
BAMC	Brooke Army Medical Center	771	278	36.1
EAMC	Eisenhower Army Medical Center	434	115	26.5
MAMC	Madigan Army Medical Center	1225	334	27.3
MGMC	Malcolm Grow Medical Center	596	129	21.6
NMCP	Naval Medical Center Portsmouth	957	231	24.1
NMCSO	Naval Medical Center San Diego	1488	646	43.4
NNMC	National Naval Medical Center	1161	105	9.0
WHMC	Wilford Hall Medical Center	826	252	30.5
WRAMC	Walter Reed Army Medical Center	3323	828	24.9
Overall	CPDR National Database	10781	2918	27.1

curative intent [2–4]. Options include radical prostatectomy (RP) with or without nerve-sparing to preserve potency, as well as external beam radiotherapy, radioactive seed implant brachytherapy and watchful waiting [5–7]. The use of RP by urologic surgeons has increased dramatically between the mid-1980s and late 1990s [8–9]. Multiple single centers of excellence have reported improved outcomes over time in the PSA-Era including the lowering of stage, shorter operative times, less blood loss, and fewer complications [10–11].

Despite the documentation of RP outcomes over time in the PSA-Era from centers of excellence, very little has been written documenting these changes from a broad cohort of patients, outside of academic centers, particularly related to blood loss and transfusion. The Department of Defence Center for Prostate Disease Research (DoD) (CPDR) Database [12] is now sufficiently mature with a large cohort of RP patients enrolled over the last decade to allow meaningful analysis of time trends of demographic, surgical, and estimated blood loss (EBL)/transfusion data.

The goal of this cohort study is to determine the changes related to radical prostatectomy within the last decade regarding EBL and transfusion data and to determine factors significantly associated with EBL. We herein report the largest reported multicenter study of radical prostatectomy documenting these changes in the PSA-Era.

## 2. Materials and methods

The clinical information and follow-up have been collected as part of the DoD CPDR Tri-Service Multicenter Prostate Disease Research Database as described previously by Sun et al. [12]. Briefly, standardized data collection forms for prostate biopsy, registration, staging, surgery, surgical pathology, radiation treatment, hormonal treatment, cryotherapy, follow-up, and necropsy have been developed and were used. Data was collected and entered by physicians and data managers, then maintained in a relational

database using MicroSoft (MS) Access software as the front end and Oracle software as the back end. The CPDR Database has been approved by the Uniformed Services University Research Administration, Institutional Review Board (IRB) as well as the IRBs of all participating military

Table 2  
Demographic factors in 2918 RP patients operated between 1985–2000 in this study

	Number	Percent (%)
Age		
≤50	138	4.7
51–60	784	26.9
61–70	1623	55.7
>70	369	12.7
Race		
White	2150	74.4
African American	575	19.9
Other	166	5.7
Clinical stage (1992 TNM)		
T1a/b	102	3.5
T1c	1138	39.5
T2a	869	30.2
T2b	523	18.2
T2c	206	7.2
T3	41	1.4
Pretreatment PSA		
0–4.0	684	24.7
4.1–10.0	1448	52.3
10.1–15.0	327	11.8
15.1–25.0	184	6.7
>25.0	125	4.5
Biopsy Gleason		
≤4	400	17.0
5–6	1316	55.9
7	499	21.2
8–10	138	5.9
Surgical era		
1985–1989	207	7.1
1990–1993	750	25.7
1994–1997	1049	35.9
1998–2000	912	31.3
Operative type		
Retropubic	2399	82.7
Perineal	501	17.3

hospitals. The original protocol in use between 1991 through 1998 did not require patients to sign a formal informed consent document. However, between 1998 and 1999, the IRBs of all sites required patient informed consent to participate. Data were allowed to be maintained on all entered data before 1998 through 1999 (exact date varies by institution) without gaining the patients' informed consent; however, no new information on existing living patients or new enrollees was entered without consent after these dates.

The data query for this study was performed in December 2001. At this time, the overall database contained 345,954 clinical records (i.e., TRUS/biopsy, staging, radical prostatectomy, follow-up, etc.) on 15,063 patients. Of these 5210 total patients, 2918 underwent a primary RP between January 1, 1985 and December 31, 2000 (16 years) with complete information of estimated blood loss and were used for this study. Table 1 provides the CPDR sites, the total number of RP cases included in this study, and the percentage of these cases of their entire enrolled cohort during the study interval.

The data fields analyzed for this study included patient age at surgery, ethnicity/race, clinical stage at diagnosis, pretreatment prostate-specific antigen (PSA) value, biopsy Gleason grade, type of radical prostatectomy (retropubic vs. perineal), nerve sparing surgical status, operative time (hours), estimated blood loss (cubic centimeters), pathologic stage, nodal disease status, surgical margin status, percentage of autologous blood donated, percentage of blood transfusion, blood transfusion type, and whether neoadjuvant hormonal therapy was administered. Descriptive statistics were used to analyze trends over time in four surgical eras: 1985 through 1989, 1990 through 1993, 1994 through 1997, and 1998 through 2000. Furthermore, multiple linear regression analysis was used to determine factors associated with blood loss. Age at surgery, operative time, surgery year, biopsy Gleason grade, and log-transformed pretreatment PSA were continuous variables. Operative approach (retropubic vs. perineal), lymphadenectomy status (yes vs. no), surgical margin status (positive vs. negative), nerve sparing surgical status (yes vs. no), race (black vs. not black), clinical stage (T1 vs. T2 versus T3), and neoadjuvant hormonal therapy (yes vs. no) were categorical variables.

### 3. Results

Table 2 provides the demographics and clinical features of the 2918 RP patients included in the study. More than 82% of men were between 50 and 70 years of age at the time of surgery, 74.4% were White, 69.7% were clinical T1c or T2a, 77% had pretreatment PSA values of less than or equal to 10.0 ng/mL, 94.1% had a biopsy Gleason grade sum of  $\leq 7$ , and 82.7% underwent a retropubic operation. With the exception of only 7.1% of the cohort operated on between 1985 through 1989, the remaining surgical era groups were relatively evenly matched.

Table 3  
Surgical factors in 2918 radical prostatectomy patients operated between 1985–2000

	Number	Percent (%)
Estimated blood loss (cc)		
$\leq 500$	601	20.6
$>500-\leq 1000$	994	34.1
$>1000-\leq 1500$	577	19.8
$>1500-\leq 2000$	309	10.6
$>2000-\leq 2500$	199	6.8
$>2500-\leq 3500$	157	5.4
$>3500-\leq 4500$	62	2.1
$>4500$	19	0.6
Operative time (hrs)		
$\leq 3$	564	24.2
$>3-\leq 4$	808	34.6
$>4-\leq 6$	846	36.3
$>6$	115	4.9
Autologous units collected		
No	1615	57.2
Yes	1211	42.8
Pathologic stage		
$\leq T2$	1725	60.5
T3a	659	23.1
T3b	209	7.3
T3c	220	7.7
T4a-b	40	1.4
Nodes status		
N0	2843	97.4
N1–N2	75	2.6
Margin status		
Neg	2034	69.7
Pos	884	30.3
Lymphadenectomy		
No	610	21.8
Yes	2187	78.2
Nerve-sparing		
Unilateral	445	18.6
Bilateral	765	32.0
No	1180	49.4
Blood transfusion type		
Autologous only	892	31.4
Homologous only	151	5.3
Autologous + Homologous	144	5.1
None	1656	58.2

In Table 3, the cohort is examined for surgical factors. Most notably, 54.7% had an estimated blood loss (EBL) of  $\leq 1000$  cc and only 8.1% had an EBL of  $>2500$  cc. 42.8% men donated autologous blood. Surgical pathologic results included 60.5% with organ-confined disease ( $\leq pT2$ ), 97.4% with negative nodes (NO) and 69.7% with negative surgical margins. Lymphadenectomy was performed in 78.2%, and unilateral or bilateral nerve sparing in 50.6%. Fully, 43.3% of men were known to have received autologous or homologous transfusion (31.4% of men received autologous transfusion and 5.3% received homologous transfusion).

Table 4 examines changes in demographic and surgical factors over time in the four time intervals during the study.

Table 4  
Time trend in demographic and selected surgical factors in 2918 radical prostatectomy patients

	1985–1989	1990–1993	1994–1997	1998–2000	<i>P</i> value
Median age (years)	66.2	64.7	62.6	62.3	< 0.001
Median PSA level (ng/mL)	5.1	7.1	6.1	5.6	< 0.001
Biopsy Gleason					0.11
% ≤6	76.1	76.9	71.9	71.3	
% ≥7	23.9	23.1	28.1	28.7	
Clinical Stage					< 0.001
% c T1	13.6	26.9	50.2	54.9	
% c T2	84.5	71.6	48.3	43.9	
Surgery type					< 0.001
% Retropubic	98.5	90.0	67.8	90.4	
% Perineal	1.5	10.0	32.2	9.6	
Median operative time (hs)	5.0	4.1	3.7	3.5	< 0.001
Median EBL (cc)	1800	1300	900	800	< 0.001
% Pts. auto blood coll.	81.7	65.7	50.1	10.9	< 0.001
% Transfusion pts.	93.2	70.9	41.6	13.7	< 0.001
Pathology stage					< 0.001
% <=p T2	55.3	58.5	57.9	66.2	
% >=p T3	44.7	39.3	40.3	33.2	
% Margin positive	33.3	32.1	32.0	26.1	0.011
% Having PLND	97.0	93.8	67.5	73.1	< 0.001

EBL = Estimated blood loss; Auto = Autologous; PLND = Pelvic lymph node dissection.

There was a significant decline in age at RP, pretreatment PSA value since 1990, clinical stage disease, median operative time, median EBL, percentage of autologous donated, percentage of blood transfusion, pathologic stage T3, margin positivity, and pelvic lymphadenectomy being performed. Table 5 shows the univariate analysis of factor associated with EBL. Operative approach, pathologic stage, margin status, lymphadenectomy, and neoadjuvant hormonal therapy were associated with EBL. Operative time, surgical year and biopsy Gleason Sum were linear correlated with EBL. In multiple linear regression analysis operative time ( $P < 0.0001$ ), surgical approach ( $P < 0.0001$ ), surgical year ( $P < 0.0001$ ), lymphadenectomy ( $P = 0.006$ ), and neoadjuvant hormonal therapy ( $P = 0.048$ ) were significant predictors of EBL.

Fig. 1 shows the mean EBL by single year intervals over the 16-year study interval; there was a dramatic decline between 1985 and 1995 and the blood loss has remained relatively constant between 1996 through 2000. Fig. 2 examines median EBL by surgical approach. There was a dramatic improvement in EBL for the retropubic prostatectomy and a slight worsening of EBL for the perineal approach. Between 1997 and 2000 there was an insignificant difference in EBL between surgical approaches. Fig. 3 illustrates the association of operative time and EBL over time. Regardless of the year, shorter operative time was associated with less blood loss. However, over the last few years, even longer operations were associated with less bleeding than in past years. Fig. 4 illustrates that median EBL was similar regardless of lymphadenectomy status in recent years. Fig. 5 shows the percentage of patients elect-

ing to donate autologous blood and receiving blood transfusion from 1990 to 2000. Between 1990 through 1994, approximately 60% of men elected to donate their own blood collection for use in RP. There was a steady decline in autologous blood collection between 1995 through 1998 and over the last 3 years, only about 10% of men elected this procedure. Blood transfusion had the same trend over the year. Fig. 6 shows the percentage of patients who were transfused autologous blood only, autologous plus homologous and homologous only blood. There was a steady decline in autologous blood transfusion from 1990 to 2000. The percentage of patients received autologous blood only was less than 10% from 1998 to 2000.

#### 4. Discussion

The most important findings of this study are that blood loss associated with radical prostatectomy and transfusion has declined sharply in the last decade as evidenced from this broad United States experience. Median EBL went from 1800 cc in the 1985 to 1989 period to 800 cc in the 1998 through 2000 interval. This improvement was found to be because of the decreased operative time, lower stage patients undergoing the operation, lessened use of lymphadenectomy and surgical approach. Specifically related to surgical approach, our findings are novel. Over the entire study, perineal RP was associated with less EBL. However, this is the first report, to our knowledge, to show an equilibration in EBL between perineal and the more common retropubic RP. By the later time interval, both approaches had a me-

Table 5  
Univariate analysis of factors associated with EBL in 2918 RP patients between 1985–2000

	Mean	Median	Range	P Value
Age				0.052
<50	1142.1	800	100–4500	
50.1–60	1152.9	900	100–5000	
60.1–70	1190.3	1000	50–5000	
>70	1232.0	1000	100–5000	
Biopsy Gleason				0.0004
≤4	1315.9	1000	100–4500	
5–6	1135.4	900	50–5000	
7	1209.6	1000	50–5000	
8–10	1148.6	1000	100–4300	
Operative time (h)				< 0.0001
≤3	846.5	650	50–4800	
>3–≤4	1093.4	900	100–5000	
>4–≤6	1496.9	1200	100–5000	
>6	1927.9	1700	50–5000	
Surgery year				< 0.0001
1985–1989	2116.1	2000	100–5000	
1990–1993	1535.7	1325	101–5000	
1994–1997	1152.3	900	50–5000	
1998–2000	968.6	800	50–5000	
Race				0.01
White	1187.0	1000	50–5000	
African-American	1210.8	900	120–4500	
Other	1037.1	800	120–4500	
Clinical stage				0.41
T1	1180.1	957.5	100–5000	
T2	1190.3	1000	50–5000	
T3	964.5	800	200–3100	
Operative type				< 0.0001
Retropubic	1358.0	1100	50–5000	
Perineal	676.3	600	50–5000	
pT stage				0.003
T2	1199.7	1000	50–5000	
T3	1295.4	1000	100–5000	
Margin status				0.007
Neg	1295.8	1000	50–5000	
Pos	1191.9	950	100–5000	
Lymphadenectomy				< 0.0001
No	891.3	700	50–5000	
Yes	1328.1	1100	50–5000	
Nerve-sparing				0.055
No	1214.8	1000	50–5000	
Yes	1236.9	1000	100–5000	
Neoadjuvant				< 0.0001
No	1257.6	1000	50–5000	
Yes	979.3	800	100–5000	

dian EBL of approximately 800 cc. We attribute this finding in our health system to a lessened use of perineal RP more recently resulting in lessened surgical experience and higher EBL. In this broad experience, the traditional blood loss advantage to perineal RP [13,14] has generally disappeared.

There are a number of other findings that deserve special comment. Notably, what is the “accepted” EBL for contemporary RP? Less than 15% of patients in this 16-year interval had an EBL of greater than 2000 cc and 8.1% had an

EBL of >2500 cc. Our recent results compare favorably to other contemporary series. Lepor et al. reported a mean EBL of  $818.6 \pm 14.9$  cc in 1000 RPs performed between 1994 and 2000 [11]. Similarly, Goh et al. reported mean EBL of approximately 750 cc in 200 RPs from the mid 1990s and Goad et al. reported median EBL going from 1200 to 800 cc in 300 cases between 1983 and 1992 [15,16]. Although bleeding in excess of 2000 cc will occasionally occur with the best surgeons, a surgeon who exceeds 2000 cc on a more than occasional basis may be subject to scrutiny.

Another common area of controversy is the issue of autologous blood. To our knowledge, this is the first study to document the rapid decline in autologous blood collection and donation over the PSA-Era. Although autologous blood donation is still recommended routinely in Japan [18] and is mandated for discussion to patients in Germany [19], recent studies from the United States discourage the practice [15,16,20]. Specifically, Goh et al. and Goad et al. found homologous transfusion rates at 5% and 11%, respectively, in more recent years because of lower EBL and autologous blood donation did not significantly alter this risk [12,13]. Similarly, Goldschlag et al. from Johns. Hopkins found that homologous transfusion was required in 1% of autologous donors and 3.5% of nonautologous donors ( $P = 0.18$ ) and concluded that the practice did not alter risk of homologous transfusion [20]. It must be mentioned that these studies [15,16,20] were all from U.S. centers-of-excellence with cases derived from well known surgical experts. Our broad practice data supports these recommendations. Although autologous blood donation was still done by approximately 10% of RP patients between 1998 through 2000, it is no longer routinely recommended at any of the participating centers. If a patient still desires autologous blood donation, we will generally authorize such collection of up to 2 units.

There are a number of limitations to this study. Estimated blood loss was *estimated* based on the CPDR clinical report form used by surgeons and data managers and with data generated from the operative anesthesia and/or operative reports. While there was no standardized way to assess EBL, i.e., sponge weights, there is no evidence that the error in standard estimation would have changed over time. Therefore, the era changes are of considerable value. Because of the structure of the database, we were not able to analyze blood loss by the experience level of the surgeon. We were also unable to analyze the autologous blood donor patients with respect to postoperative hematocrit, blood loss, length of hospital stay, and quality of life which would have added to the value of the review. Despite these limitations, this is the largest and only multicenter study of blood loss and changes during the PSA-Era. These data will be useful for quality assurance benchmark assessment in contemporary radical prostatectomy outcome studies. Furthermore, with the current emergence of laparoscopic radical prostatectomy, this data on open RP may be useful for comparison.

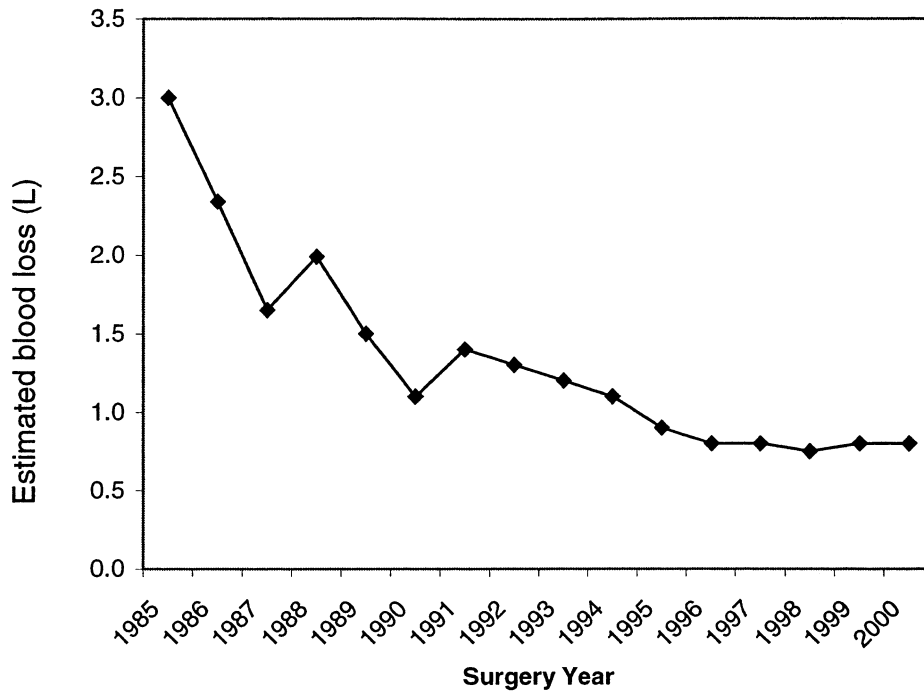


Fig. 1. Trend of median blood loss in 2918 radical prostatectomies between 1985 and 2000.

**5. Conclusions**

Clinically localized prostate cancer is the predominantly diagnosed stage of disease in the PSA-Era and radical prostatectomy is a very commonly performed operation. Current era patients are typically younger (early 60s) with the clin-

ical stage T1 disease and a pretreatment PSA level less than 10 ng/mL. As a result, surgery is generally performed in less than 3.5 h with blood loss less than 1000 cc. The traditional blood loss advantage of perineal prostatectomy has disappeared in this study and retropubic prostatectomy was also associated with low EBL.

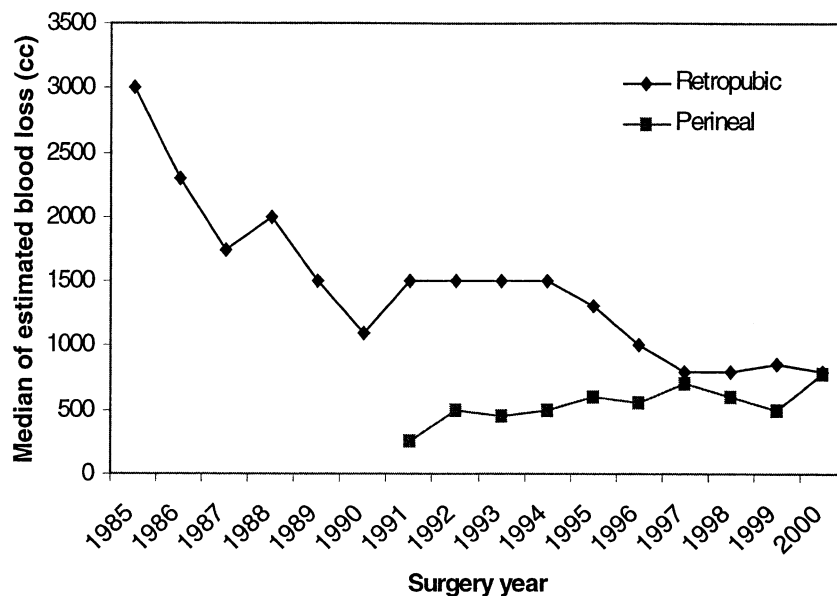


Fig. 2. Surgical approach and blood loss in 2918 radical prostatectomies between 1985–2000.

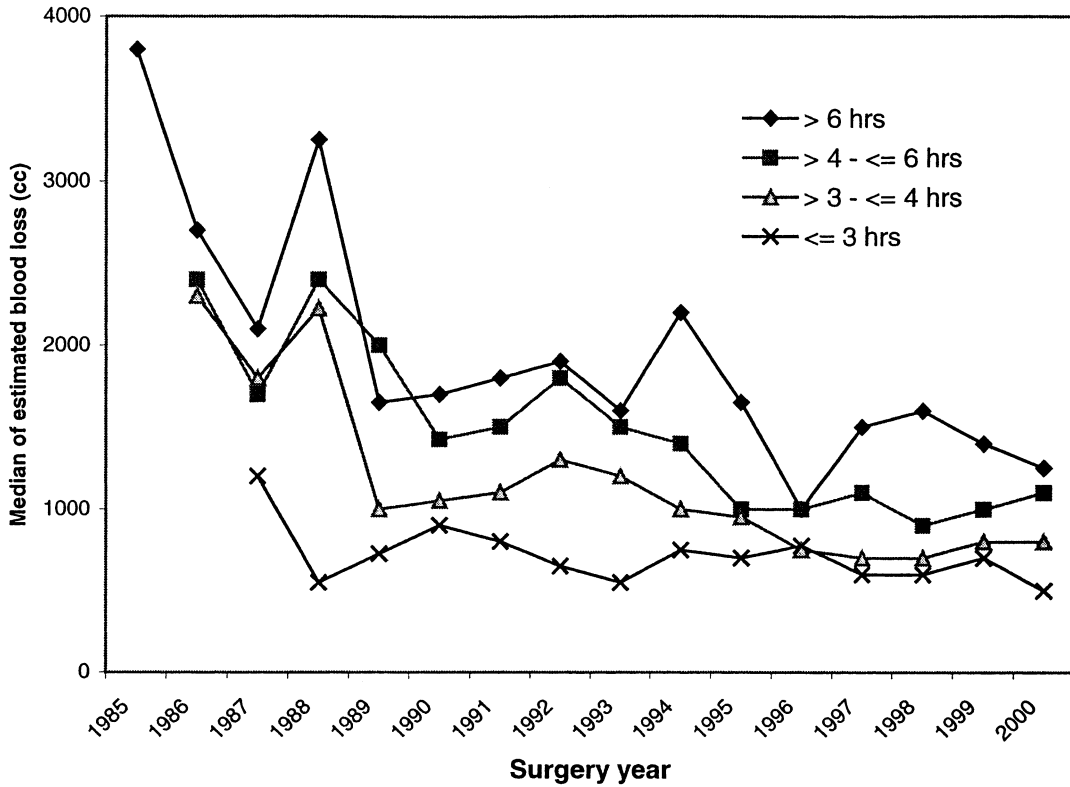


Fig. 3. Operative time and blood loss over time in 2918 radical prostatectomies.

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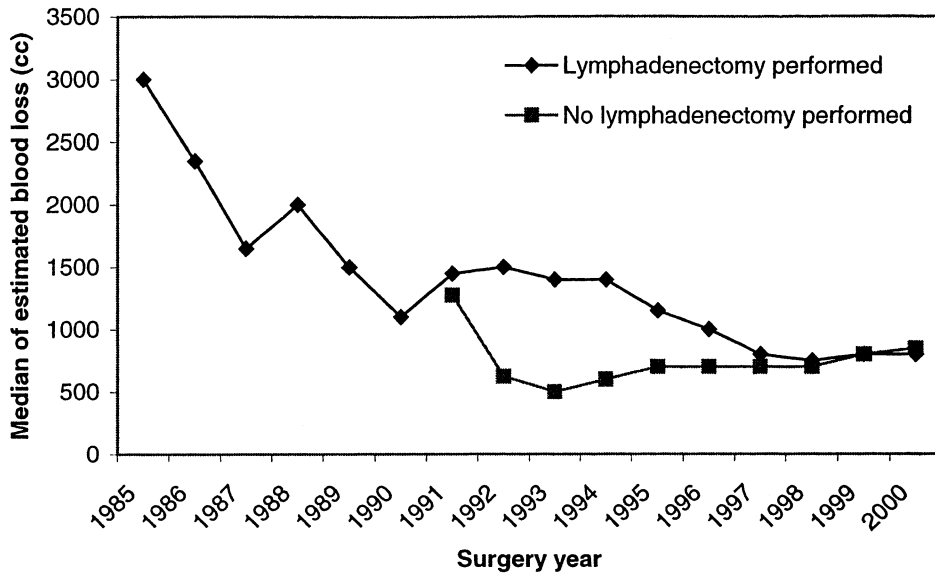


Fig. 4. Lymphadenectomy performed in conjunction with radical prostatectomy impacts on EBL over time.

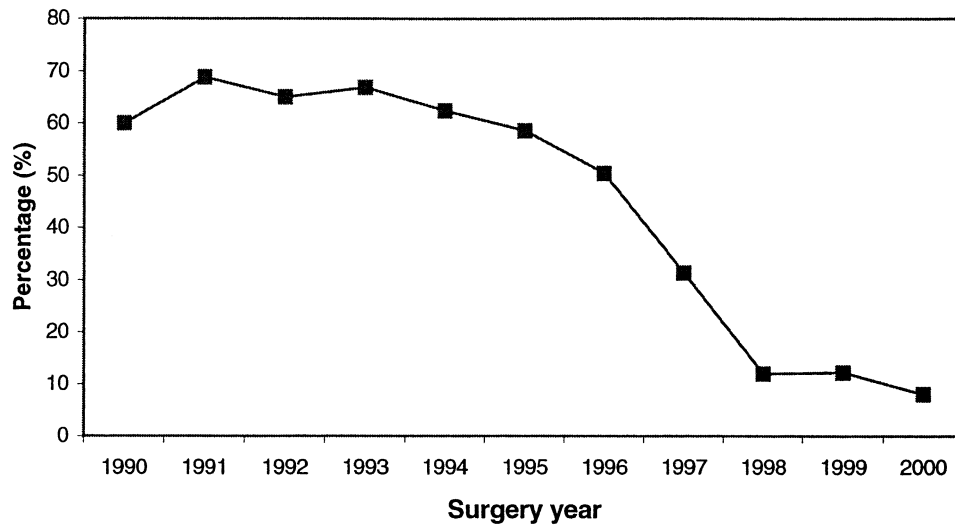


Fig. 5. Percentage of patients having autologous blood collection and any blood transfusion over time.

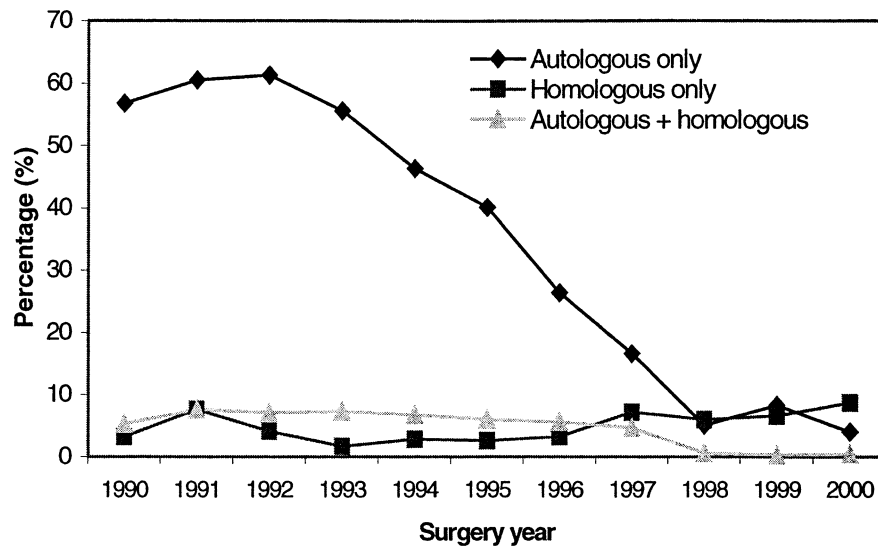


Fig. 6. Percentage of patients getting autologous only, homologous only, and autologous plus homologous blood transfusion over time.

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