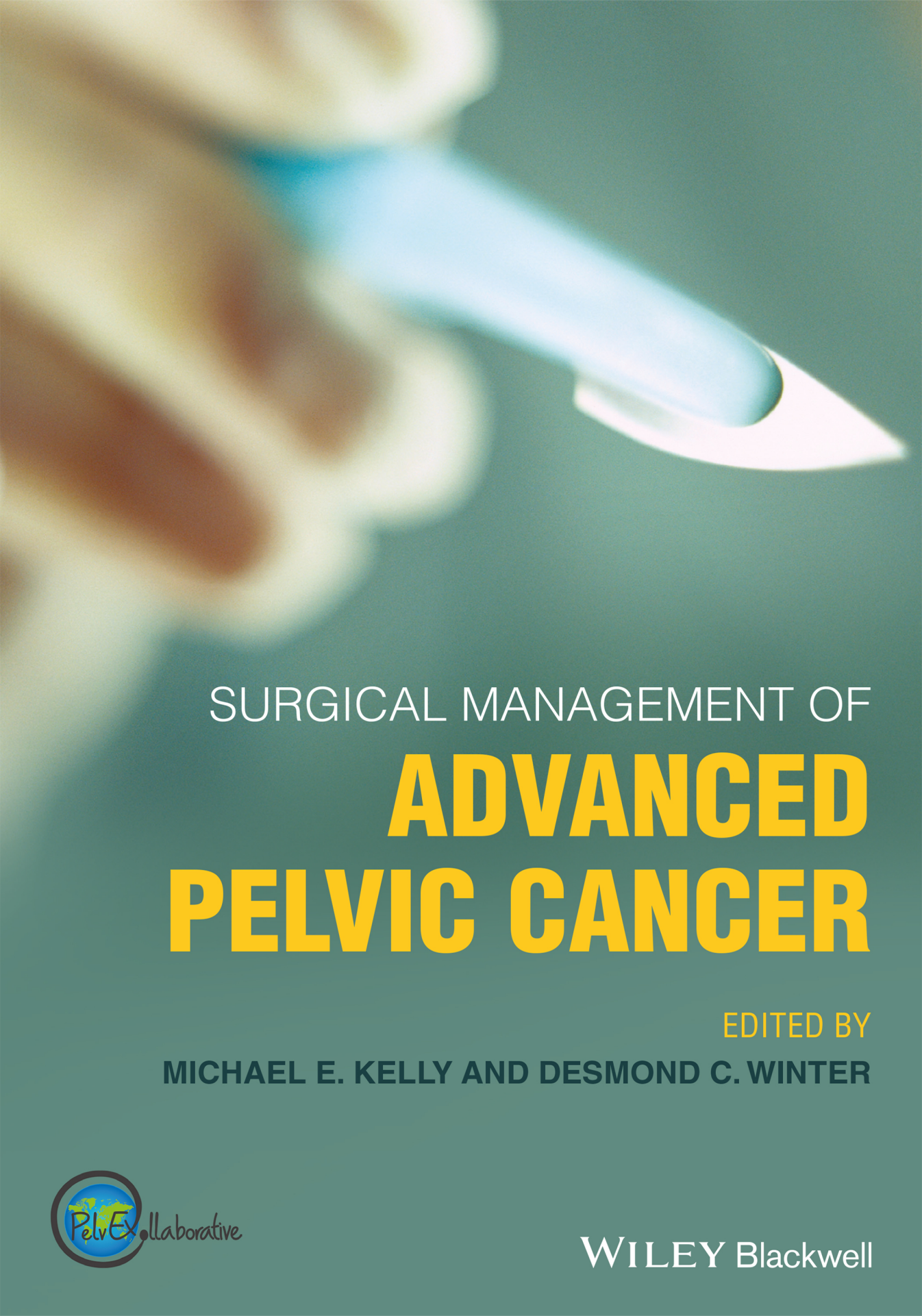

SURGICAL MANAGEMENT OF ADVANCED PELVIC CANCER

EDITED BY

MICHAEL E. KELLY AND DESMOND C. WINTER

PelvEx Collaborative

WILEY Blackwell

Surgical Management of Advanced Pelvic Cancer

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Edited by Michael E. Kelly and Desmond C. Winter

St. Vincent's University Hospital
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Contents

List of Contributors

Arend Aalbers, MD
Netherlands Cancer Institute, Amsterdam, The Netherlands

Gordon Beadel, MB, FRACS
Department of Orthopedic Surgery, Christchurch Hospital, Christchurch, New Zealand

Brian K. Bednarski, MD, MEd, FACS
Department of Surgical Oncology, University of Texas MD Anderson Cancer Center, Houston, Texas, USA

Geerard Beets, MD, PhD
Netherlands Cancer Institute, Amsterdam, The Netherlands

Brian Bird, BA, MB, FRCPI
Department of Medical Oncology
Bons Secours, Cork, Ireland

Patrick Boland, MD, FRCS(I), FRCS
Orthopaedic Service, Department of Surgery at Memorial Sloan Kettering Cancer Center, New York; City, USA

Maximilian Brunner, MD
Department of Surgery, University Hospital Erlangen, Friedrich-Alexander-Universität Erlangen-Nürnberg, Erlangen, Germany

Jacobus W.A. Burger, MD, PhD
Department of Surgery, Catharina Hospital Eindhoven, The Netherlands

David Burling, MBBS MRCP FRCR
Department of Gastro-Intestinal Radiology, Complex Cancer Clinic, St. Mark's Hospital, London, UK

George J. Chang, MD, MS
Department of Surgical Oncology, University of Texas MD Anderson Cancer Center, Houston, Texas, USA

Timothy Chittleborough, MBBS, DMedSc, FRACS
Colorectal Surgery Unit, The Royal Melbourne Hospital, Melbourne, Victoria, Australia

Henrik Kidmose Christensen, MD
Aarhus University Hospital, Denmark

Marta Climent, MD, PhD
Department of Surgery, Bellvitge University Hospital, Barcelona, Spain

Danielle Collins, MB, MD, FRCSI
Edinburgh Colorectal Unit, Western General Hospital, Edinburgh, UK

Alex Colquhoun, MD, FRCS(Urol)
Department of Surgery, Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK

Ben Creavin, MB, MD, MRCSI
St. Vincent's University Hospital, Dublin, Ireland

Ian Daniels, FRCS
Exeter Surgical Health Service Research Unit (HeSRU)/University of Exeter Medical School, Exeter, UK

R. Justin Davies, MA, MB MChir, LRCP, FRCS, FEBS, FASCRS
Department of Surgery, Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK

Meara Dean, MBBS (Hons), MPH, MSurg, FRACS, FRCS
Department of Surgery, Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK

Martyn Evans, BM, MPhil, FRCS
Department of Surgery, Morriston Hospital, Swansea, Wales, UK

Nicola S. Fearnhead, BM, DM, FRCS
Department of Surgery, Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK

Peter Featherstone, MB, BSc(Hons), MRCP, FRCA, FFICM
Department of Intensive Care Medicine and Anaesthesia, Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK

Frank Frizelle, MBChB, MMedSci, FRACS, FACS, FASCRS, FNZMA, FRCSI (Hon)
Department of Surgery, University of Otago and Christchurch Hospital, Christchurch, New Zealand

Mark George, BSc, MS, FRCS
Department of Colorectal Surgery, St. Thomas' Hospital, London, UK

Jan W.A. Hagemans, MD
Department of Surgery, Erasmus MC, Rotterdam, The Netherlands

Dean Harris, MD, FRCS
Department of Surgery, Morriston Hospital, Swansea, Wales, UK

Paul K. Hegarty, MD, FRCS Urol
Department of Urology, Mater Hospital, Cork, Ireland

Alexander G. Heriot, MB, MA, MD, MBA, FRCSEd, FRACS
Department of Surgical Oncology, Peter MacCallum Cancer Centre, Melbourne, Australia

Werner Hohenberger, MD
Department of Surgery, University Hospital Erlangen, Friedrich-Alexander-Universität Erlangen-Nürnberg, Erlangen, Germany

Nisha Jagasia, MB, FRANZCOG, CGO, GradDipPallC
Department of Gynecological Oncology, Mater Adults Hospital, Brisbane, Australia

Awad M. Jarrar, MD
Department of Colorectal Surgery, Cleveland Clinic, Cleveland, OH, USA

John T. Jenkins, BSc MD FRCS FEBC
Department of Surgery, Complex Cancer Clinic, St. Mark's Hospital, London, UK

Päivi Kannisto, MD, PhD
Department of Obstetrics and Gynecology, Skåne University Hospital, Lund, Sweden

Michael E. Kelly, BA, MB, MCh, EBSQ (Coloproctology), FRCSI
Department of Colorectal Surgery, St. Vincent's University Hospital, Dublin, Ireland

Paul Kelly, BA, MB, FFRCSI
Department of Radiation Oncology Bons Secours, Cork, Ireland

Cherry Koh, MB (Hons), MS, FRACS
Surgical Outcomes Research Centre (SOuRCe); RPA Institute of Academic Surgery; Department of Colorectal Surgery, Royal Prince Alfred Hospital, Sydney, New South Wales, Australia; Discipline of Surgery, Central Clinical School, Sydney Medical School, University of Sydney, Sydney, New South Wales, Australia

Niels Kok, MD, PhD
Netherlands Cancer Institute, Amsterdam, The Netherlands

Rory Kokelaar, MA, MEd, MRCS
Department of Surgery, Morriston Hospital, Swansea, Wales, UK

Christos Kontovounisios, MD, PhD, FACS, FRCS
Department of Colorectal Surgery, Chelsea and Westminster NHS Foundation Trust, London, UK; Department of Surgery and Cancer, Imperial College, London, UK; Department of Colorectal Surgery, Royal Marsden Hospital, London, UK

Hidde M. Kroon, MD, PhD
Colorectal Unit, Department of Surgery, Royal Adelaide Hospital, Adelaide, Australia; Faculty of Health and Medical Science, School of Medicine, University of Adelaide, Adelaide, Australia

Ka On Lam, MBBS(HK), FRCR, FHKCR, FHKAM (Radiology)
Department of Clinical Oncology, Faculty of Medicine, University of Hong Kong, Hong Kong

Wai Lun Law, MB, MS, FRCSEd, FCSHK, FHKAM (Surgery)
Department of Surgery, Faculty of Medicine, University of Hong Kong, Hong Kong

Fredrik Liedberg, MD, PhD
Institution of Translational Medicine, Lund University, Malmö, Sweden; Department of Urology, Skåne University Hospital, Malmö, Sweden

Marie-Louise Lydrup, MD, PhD
Division of Surgery, Department of Clinical Sciences, Lund University, Skåne University Hospital, Malmö, Sweden

Andrew C. Lynch, MBChB, MMedSci, FRACS, FCSSANZ
Department of Surgical Oncology, Peter MacCallum Cancer Centre, Melbourne, Australia

Frank McDermott, MD, FRCS
Exeter Surgical Health Service Research Unit (HeSRU)/University of Exeter Medical School, Exeter, UK

John McGrath, FRCS
Exeter Surgical Health Service Research Unit (HeSRU)/University of Exeter Medical School, Exeter, UK

Akash M. Mehta, MD
Department of Surgery, Complex Cancer Clinic, St. Mark's Hospital, London, UK

Susanne Merkel, MD
Department of Surgery, University Hospital Erlangen, Friedrich-Alexander-Universität Erlangen-Nürnberg, Erlangen, Germany

Gregory J. Nason, MSc, FRCS Urol, FEBU
Division of Uro-Oncology, University of Toronto, Ontario, Canada

Joost Nederend, MD, PhD
Department of Radiology, Catharina Hospital Eindhoven, The Netherlands

Clare O'Connell, MSc, MRCSI
Department of Urology, Tallaght University Hospital, Dublin 24, Ireland

Dimitrios Patsouras, MSc, PhD, FRCS
Department of Colorectal Surgery, St. Thomas' Hospital, London, UK

Shahnawaz Rasheed, BClinSci, MBBS, DIC, PhD, FRCS
Department of Colorectal Surgery, Royal Marsden Hospital, London, UK

P. Ronan O'Connell, MD, FRCSI, FRCS Eng, FRCPS Glas, FRCS Edin
Department of Surgery, St. Vincent's University Hospital, Dublin, Ireland; Royal College of Surgeons in Ireland, Dublin, Ireland

Miguel Pera, MD, PhD
Hospital del Mar Universidad Autónoma de Barcelona, Spain

Joost Rothbarth, MD, PhD
Department of Surgery, Erasmus MC, Rotterdam, The Netherlands

Harm J.T. Rutten, MD, PhD
Department of Surgery, Catharina Hospital Eindhoven, The Netherlands

Éanna J. Ryan, MB, MD, MRCSI
Department of Surgery, St. Vincent's University Hospital, Dublin, Ireland

Peter Sagar, MD, FRCS, FRCPS (Hon), FASCRS (Hon)
The John Goligher Department of Colorectal Surgery, St. James's University Hospital, Leeds, UK; University of Leeds, Leeds, UK

Tarik Sammour, BHB, MB, FRACS, CSSANZ, PhD
Colorectal Unit, Department of Surgery, Royal Adelaide Hospital, Adelaide, Australia; Faculty of Health and Medical Science, School of Medicine, University of Adelaide, Adelaide, Australia

Dennis. P. Schaap, MD
Department of Surgery, Catharina Hospital Eindhoven, The Netherlands

Alexis Schizas, MSc, MD, FRCS
Department of Colorectal Surgery, St. Thomas' Hospital, London, UK

Eugenia Schwarzkopf, MD
Orthopaedic Service, Department of Surgery at Memorial Sloan Kettering Cancer Center, New York; City, USA

Neil Smart, MB, FRCSEd
Exeter Surgical Health Service Research Unit (HeSRU)/University of Exeter Medical School, Exeter, UK

Michael Solomon, DMed, DMedSc, MSc, FRACS, FRCSI
Surgical Outcomes Research Centre (SOuRCe); RPA Institute of Academic Surgery; Department of Colorectal Surgery, Royal Prince Alfred Hospital, Sydney, New South Wales, Australia; Discipline of Surgery, Central Clinical School, Sydney Medical School, University of Sydney, Sydney, New South Wales, Australia

Mette Møller Sørensen, MD, PhD
Aarhus University Hospital, Denmark

Scott R. Steele, MD, MBA
Department of Colorectal Surgery, Cleveland Clinic, Cleveland, OH, USA

Daniel Steffens, BPhty (Hons), PhD
Surgical Outcomes Research Centre (SOuRCe), Royal Prince Alfred Hospital, Sydney, New South Wales, Australia

Paris Tekkis, BMedSci, BM, MD, HonD, FRCS
Department of Colorectal Surgery, Chelsea and Westminster NHS Foundation Trust, London, UK; Department of Surgery and Cancer, Imperial College, London, UK; Department of Colorectal Surgery, Royal Marsden Hospital, London, UK

Jurriaan B. Tuynman, MD, PhD
Department of Surgery, Amsterdam UMC, Amsterdam, The Netherlands

Gabrielle H. van Ramshorst, MD, PhD
Department of Gastrointestinal Surgery, Ghent University Hospital, Ghent, Belgium

Jan M. van Rees, MD
Department of Surgery, Erasmus MC, Rotterdam, The Netherlands

Cornelis Verhoef, MD, PhD
Department of Surgery, Erasmus MC, Rotterdam, The Netherlands

Victor Jilbert Verwaal MD
Aarhus University Hospital, Denmark

Satish K. Warrier, MBBS, MS, FRACS
Department of Surgical Oncology, Peter MacCallum Cancer Centre, Melbourne, Australia

Johannes H.W. de Wilt, MD, PhD
Department of Surgery, Radboud University Hospital, Nijmegen, The Netherlands

Desmond C. Winter, MB, FRCSI, MD, FRCS (Gen)
Department of Colorectal Surgery, St. Vincent's University Hospital, Dublin, Ireland

Jeremy Yip, MBBS(HK), FRCSEd, FCSHK, FHKAM (Surgery)
Department of Surgery, Faculty of Medicine, University of Hong Kong, Hong Kong

Alexandra Zaborowski, BA, MB, MRCSI
St. Vincent's University Hospital, Dublin, Ireland

Preface

The management of advanced pelvic malignancies has evolved substantially over the last few decades. This book aims to outline all aspects of patient care, from perioperative decision-making and prehabilitation, to treatment strategies, operative approaches, and more. The topics discussed are succinctly covered by experts from around the world. Key recommendations and references highlight international consensus on optimal treatment planning.

This book is only possible by the immense effort and involvement of the entire PelvEx Collaborative network. First established in 2015, PelvEx has grown to include over one-hundred institutions across the globe. Our mission is to provide a platform for clinical studies and trials to improve perioperative and survival outcomes, while ensuring better quality of life for patients with advanced pelvic malignancy. We would like to thank everyone involved in PelvEx, the contributors who have made this book possible, and you for reading it. We hope you find it useful and informative.

Michael E. Kelly & Desmond C. Winter
On Behalf of the *PelvEx Collaborative*

1

From Early Pioneers to the PelvEx Collaborative

Éanna J. Ryan[1] and P. Ronan O'Connell[1,2]

[1] *Department of Surgery, St. Vincent's University Hospital, Dublin, Ireland*
[2] *Royal College of Surgeons in Ireland, Dublin, Ireland*

Background

Pelvic exenteration, involving radical multivisceral resection of the pelvic organs, represents the best treatment option. The first report of pelvic exenteration was in 1948 by Alexander Brunschwig of the Memorial Hospital (New York USA), as a palliative procedure for cervical cancer [1]. Due to high morbidity and mortality rates many considered palliative exenteration too radical, and it was performed only in a small number of centers in North America [2].

Technologic advancements, surgical innovations, and improved perioperative care facilitated the evolution of safer and more radical exenterative techniques for the treatment of advanced gastrointestinal and urogynecological malignancies [3]. Worldwide collaborative data [4, 5] have demonstrated that a negative resection margin is crucial in predicting survival and quality of life after surgery. Carefully selected patients who undergo en-bloc resection of contiguously involved anatomic structures with R0 resection margins can expect good long-term survival with acceptable levels of morbidity [4, 5].

The Pioneers

Eugene M. Bricker (Columbia, USA), a contemporary of Brunschwig, had been independently performing exenterative procedures beginning in 1940 [6]. Due to adverse outcomes and the interruption of World War II, his experience remained unpublished [6]. Jesse E. Thompson (Dallas, USA), one of the founders of vascular surgery as a subspecialty, and Chester W. Howe (Boston, USA) reported the first case of "complete pelvic evisceration" for locally advanced rectal cancer (LARC) in 1950. Other early advocates of the concept included Lyon H. Appleby (Vancouver, Canada), who performed a procedure he termed a "proctocystectomy" [7], and Edgar S. Brintnall (a general and vascular surgeon) and Rubin H. Flocks (an early urologist from Iowa, USA), who termed their procedure "pelvic viscerectomy" [8].

Brunschwig's Operation

While elsewhere PE was being developed principally for patients with LARC, in New York, Alexander Brunschwig was performing PE as

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a palliative procedure for locally advanced gynecologic malignancies. Before the introduction of PE, the prognosis for locally advanced cervical cancer was particularly poor. External beam radiation therapy was the mainstay of management. Local extension commonly occurred and cure rates were as low as 20% for primary disease [9]. Forty percent of deaths were the result of advanced disease confined to the pelvis [10]. Patients with end-stage malignancy suffered refractory pain, as well as intestinal and ureteric obstruction as major complications [11, 12].

Brunschwig, who had been among the first to report a one-stage radical pancreaticoduodenectomy in 1937 [1, 13], observed that PE was a "procedure of desperation since all other attempts to control the disease had failed." Initially his only selection criterion was that disease must be "confined to the pelvis." Interestingly, "not a single patient refused the operation even after detailed explanation of the procedure and the complications associated with surgery" [1]. The operative approach was similair (Figure 1.1).

Although Many surgeons were critical, considering it "a thoughtless form of mutilation, with limited chance of success for palliation, much less cure" [14]. In the earliest series, the survival outcomes were poor, with one in every three operations resulting in perioperative mortality [1, 15]. In Brunschwig's 1948 article, he reported operating on 22 patients with 5 deaths. [4].

By 1950, Bricker was also investigating the role of PE in the management of cervical cancer. His first patient, despite widespread local invasion, had a disease-free survival of 42 years [6]. The suitability of PE for the management of cervical and other gynecological cancers was later confirmed by Brunschwig in several series [16, 17]. In the ensuing decades, several units (mostly in North America) increasingly performed PE for advanced cancer of the vulva [18], ovary [19], and prostate [20], and for pelvic sarcoma [21]. The first documented non-malignant application for PE was for management of severe radiation necrosis of several pelvic organs in 1951. This remained a relatively common indication for PE until more contemporary radiation therapies became available [22].

Evolution in Pelvic Exenterative Surgery

Urinary Reconstruction

The key challenge in extended pelvic resection was urinary tract reconstruction. Though urinary diversion techniques had been described since 1852, leakage and infection issues resulted in many modifications in technique over the last century [23]. In 1909, Verhoogan and De Graeuwe (Brussels, Belgium) implanted ureters into an isolated segment of terminal ileum draining via an appendicostomy [24]. However, isolated ileal segments temporarily fell out of use [25]. Over the next three decades, Robert C. Coffey (Oregan, USA) experimented with various methods of bladder substitution by implanting ureters into the residual colon [26, 27]. Although he presented his outcomes outcomes in 1925 they were never published because "exposure of the ureters and kidneys to the fecal stream often led to sepsis, hyperchloremic acidosis, and kidney failure" [24]. Brunschwig's favored technique of "wet colostomy" was essentially reproduction of Coffey's method and suffered from the same shortcomings [22].

Other pioneers interested in this type of surgery had also attempted the creation of artificial bladders from bowel or alternatively developing cutaneous ureterostomies [22]. Appleby (Vancouver, Canada) examined the possibility of transferring both ureters to an intact cecum draining through a sigmoid colostomy, but with limited effect [7]. Similarly, Bricker created a diversion that involved isolation of a cecal segment "to be drained intermittently of urine through a catheter" [6]. Gilchrist and colleagues reported attaining successful

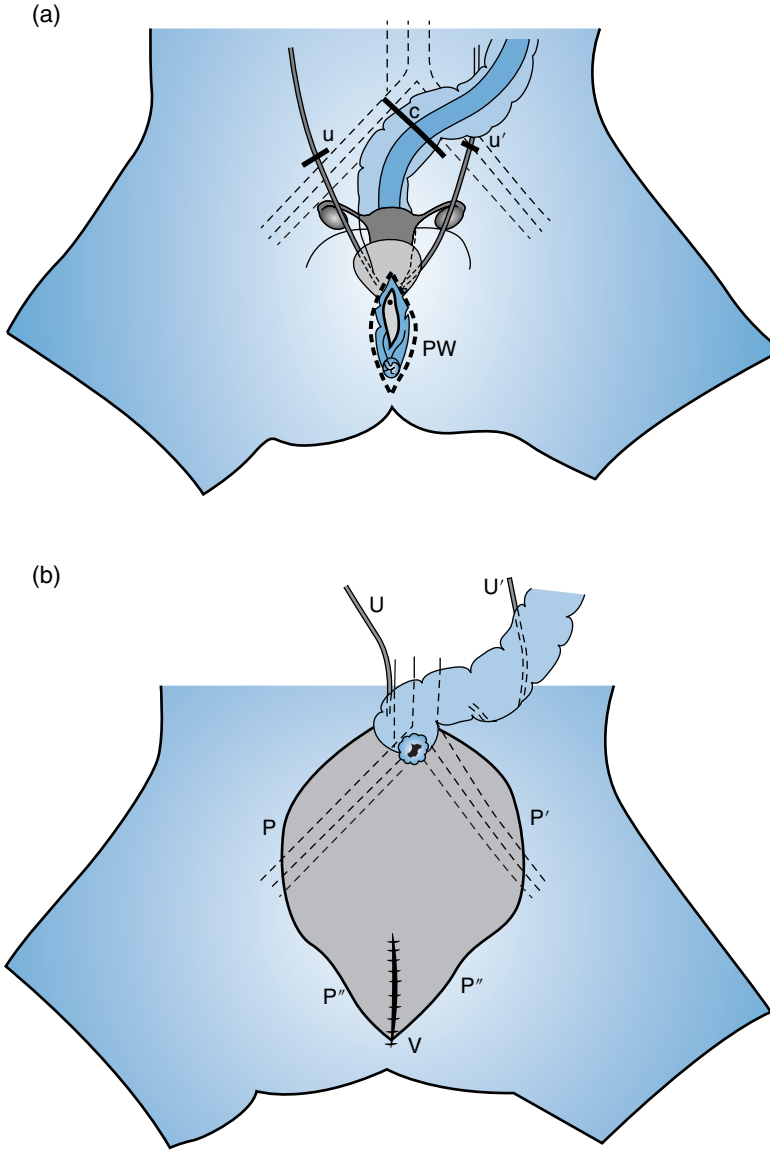

Figure 1.1 (a) Levels of transection of the ureters (U) and colon (C) and incision encompassing the vulva (V) and anus (PW) from Brunschwig's original article. (b) Conditions at end of operation, indicating areas of peritonectomy (shaded area, P, P′, PI″, and PI‴). Midline colostomy is shown with both ureters (U and U′) implanted into the colon a short distance above colostomy. Copyright © 1948 American Cancer Society. *Source:* Reproduced with permission from John Wiley & Sons Ltd. [1].

continence with the construction of an intra-abdominal reservoir from isolated cecum draining via the terminal ileum [28]. However, Bricker was unable to duplicate these results and chronic leakage of urine frustrated clinicians and patients alike (Figure 1.2) [29].

The Koenig–Rutzen Bag

In 1944, Alfred Strauss (Chicago, USA) encouraged a young engineering student named Koenig who had an ileostomy following colectomy for ulcerative colitis to develop an

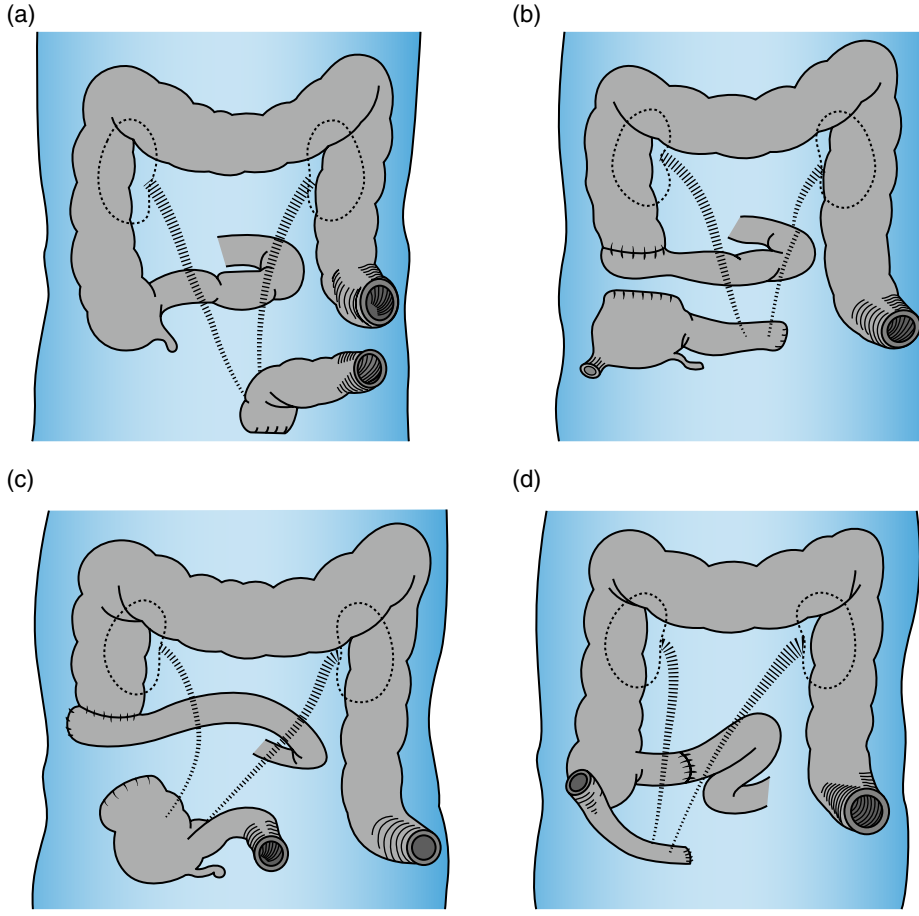

Figure 1.2 Diagram from Bricker's original article on urinary diversion demonstrating the evolution of various intestinal reconstruction techniques, including bilateral ureteric anastomosis to an isolated segment of sigmoid colon (A), terminal ileum with cecal reservoir (B), cecum with terminal ileum for urinary drainage tract (C), and contemporary ileal conduit (D). Copyright © 1950 Surgical Clinics of North America. *Source:* Reproduced with permission from Elsevier [29].

ileostomy appliance. Koenig designed a slender bag with a circular faceplate to accommodate the stoma. This was held in place with a latex sealant, Koenig formed a commercial partnership with Rutzen and the device was known as the Koenig–Rutzen bag. When Bricker heard of the device, he and his colleagues began to direct their efforts toward refining the construction of the uretero-ileal conduit [24].

Evolution of the Uretero-Ileal Conduit

By the late 1950s, the ileal conduit became the established urinary diversion technique, and the high mortality and morbidity rates associated with pelvic exenteration began to decline [30]. In particular the procedure avoided the complications of implanting ureters into an intact colon and could be fashioned from ileum that was undisturbed by any pre-existing

radiotherapeutic field [31]. Despite these benefits, the complex nature of exenterative surgery made significant postoperative complications associated with urinary diversion were considered unavoidable, particularly the development of urinary fistulas [15, 32]. Brunschwig observed that, in patients who survived > 5 years "the most frequent subsequent cause of death is the deterioration of the diverted urinary tract" [33]. He advocated continuous surveillance of the urinary diversion and for the early use of temporary or permanent nephrostomy tubes for any evidence of obstruction [33].

Today, en-bloc cystectomy is required in approximately half of all patients undergoing pelvic exenteration [34–37]. Despite much progress, postoperative urological complications remain a major cause of morbidity, prolonging hospital admission and impacting on quality of life [35]. Major complication rates between 9 and 24% are reported, with urinary leak rates occurring in 7–16% of patient [35–37]. Newer techniques for continent urinary diversion, such as the internal ileal pouch reservoir [38, 39], remain controversial. Alternatives like the Indiana pouch and the Miami pouch are suitable in highly selected patients [40, 41].

Subspecialization and Partial Exenteration

The synchronous abdomino-perineal pelvic exenteration performed by the majority of exenterative units today was adapted from the technique for LARC described by Schmitz (Chicago, USA) in 1959 [42]. Over time it was recognized that the malignancy did not always extend to all of the adjacent pelvic organs. Consequently, partial exenteration was described, preserving urinary and/or rectal function. The later part of the twentieth century also saw the intensification of surgical subspecialization, driven in part by returning surgical veterans from World War II who had gained experience in specialties such as orthopedics and plastic and reconstructive surgery. The rapid subspecialization that ensued, combined with major advances in perioperative care, including intensive care and cardiac monitoring contributed to the progress seen in exenterative surgery (Figure 1.3) [2].

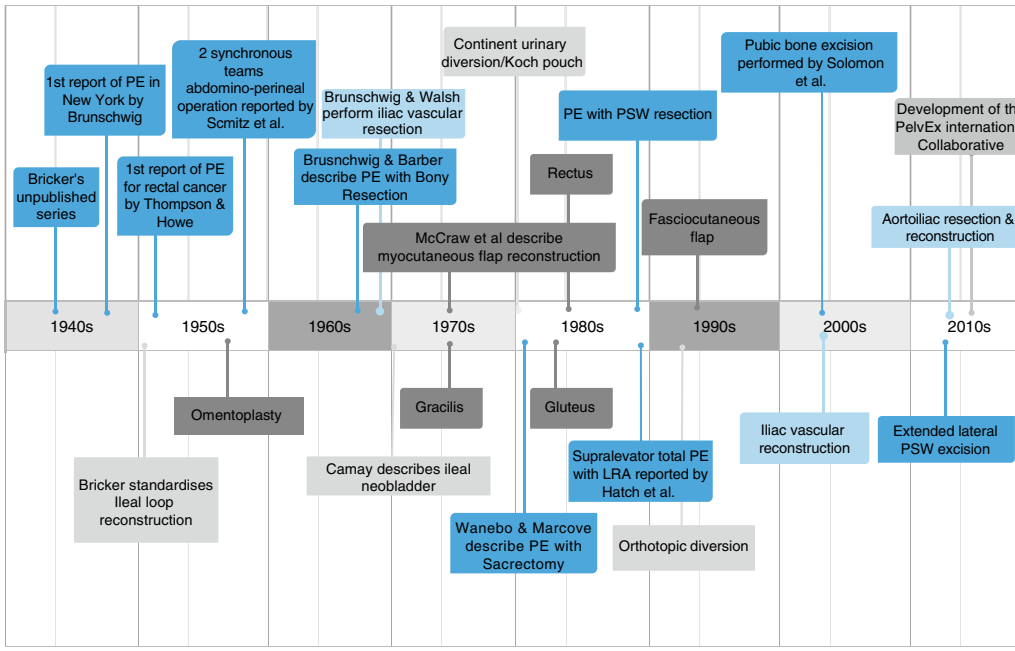

Figure 1.3 Evolution of pelvic exenterative surgery.

Composite Pelvic Exenterations

The development of compartmentalization of the pelvis and of partial exenteration resulted in more targeted approaches Bone resection was necessary for tumors involving the sacrum, coccyx, ischium, pubic symphysis, and/or ischiopubic rami [2]. Recent collaborative data show that bone resection (where needed) along with R0 margins are the most important factors influencing overall survival following PE for LRRC [5]. Disease proximal to the S1/S2 level was considered unresectable in many centers, and this represents another challenge [43–46].

Brunschwig and Barber reported a series of 28 patients, perioperative mortality was 29%, with five-year survival of 15% [47]. These initial outcomes discouraged many from pursing en-bloc bone resection. Research and better operative techniques developed for the management of sacral chordomas rekindled interest in composite PE in the 1980s [48]. Wanebo and Marcove (Charlottesville, USA) described the abdominal-trans-sacral approach for resecting LARC with sacral extension in 1981 (Figure 1.4) [49]. The initial dissection of the intrapelvic organs was accomplished through the traditional anterior approach followed by resection of the sacrum with the patient repositioned lying prone [46, 49]. Takagi and colleagues (Nagoya, Japan) encountered no postoperative mortality with this technique [50].

These outcomes stimulated research into the role of composite sacral resection for LARC and led to various units undertaking more radical resections, reporting morbidity rates between 40 and 91%, with < 5% perioperative mortality and five-year survival of almost 50% [51–55]. In recent years, specialist units developed techniques for en-bloc partial sacral resection. Hemisacrectomy, a procedure involving resection of the anterior cortex of the sacrum to preserve the sacral nerve roots, and segmental sacrectomy are alternatives [55–59].

Lateral Pelvic Sidewall Resection

Brunschwig and Walsh described "resection of the great veins of the lateral pelvic wall" to gain clearance for advanced gynecological tumors in the late 1940s [60]. However, extension of pelvic cancer into the pelvic sidewall was traditionally been considered contraindication to resection. Due to the technical difficulty of safely attaining an R0 resection margin. Efforts at vascular reconstruction were hampered by the procedure being frequently preformed in a grossly contaminated and often previously heavily irradiated field [61]. Due to these poor early outcomes, few undertook such radical resections until very recently [62].

Contemporary studies have reported en-bloc resection of the pelvic sidewall for both locally advance and recurrent rectal cancer involving the lateral pelvic neurovasculature with good outcomes [63]. Similarly, extended lateral wall resection is possible in advanced gynecological tumors [64]. Some units are providing "higher and wider" resections for tumors involving the common and external iliac vessels [65, 66] and extending to the sciatic nerve and ischial bone [2, 57, 67]. Reported R0 resection rates range from 38 to 58%, with no perioperative mortality, and 96–100% long-term graft patency [65, 66].

Perineal Reconstruction

In the original series, after the exenteration was performed, the pelvis was generally packed and allowed to heal by secondary intention. Later, surgeons closed the perineum in two layers, to prevent the small intestine prolapsing into the pelvic cavity [1]. In recent decades, various techniques for filling the "dead-space" have been examined. The omental pedicle flap was reported as an adjunct in keeping the small bowel and urinary conduit from prolapsing into the pelvic cavity, with the hope of reducing fistula rates [68, 69]. In addition, the use of mesh reconstruction of the pelvic inlet, colonic advancement, and locoregional myocutaneous flaps have been advocated with varying degrees

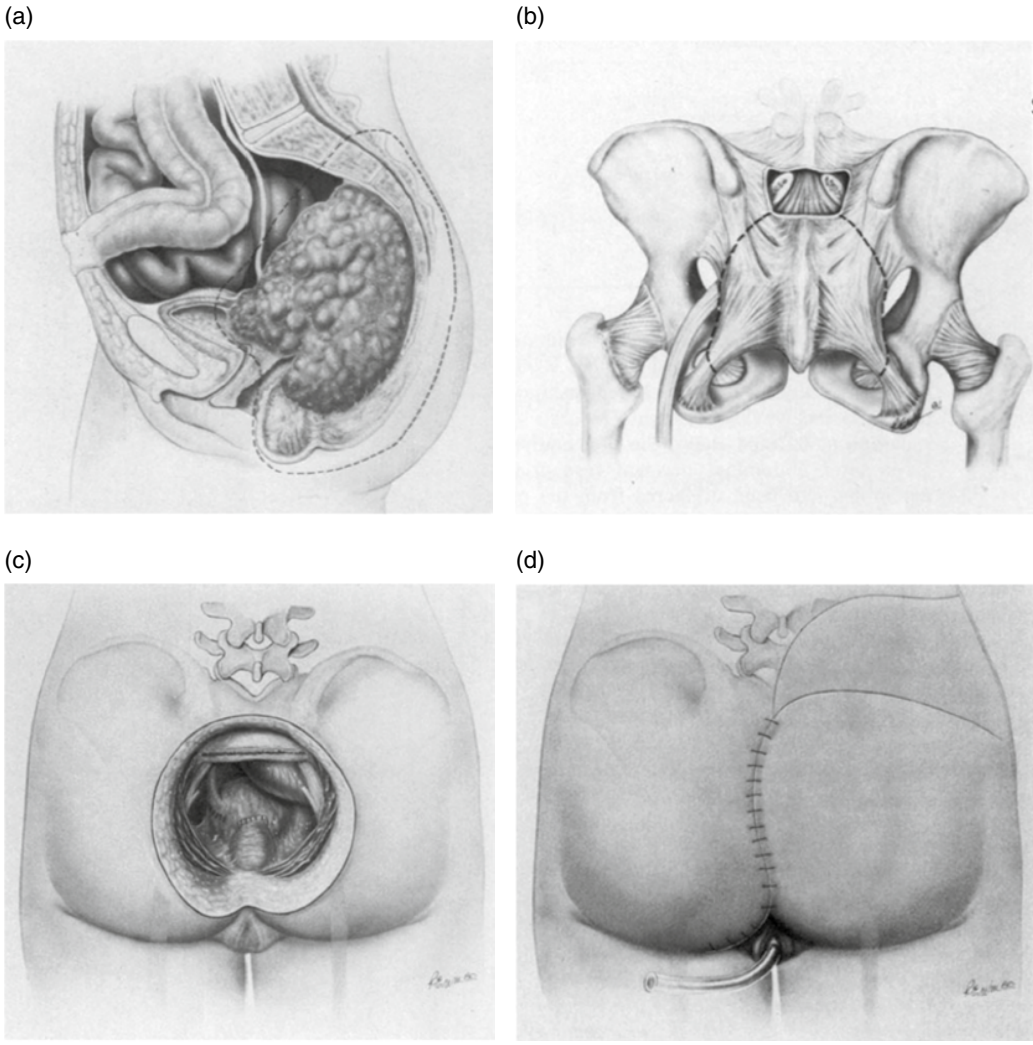

Figure 1.4 Diagrams from the first description by Wanebo and Marcove of abdomino-prone sacral resection showing the extent of resection required for recurrence of rectal cancer in the posterior compartment (A), lines of transection of the sacrum from the posterior approach (B), the operative defect after sacral resection (C), and rotational skin flaps for wound closure (D). Copyright © 1981 J.B. Lippincott Company. *Source:* Reproduced with permission from Wolters Kluwer [49].

of success (Figure 1.5) [70–72]. The use of flaps in particular was an important development that simultaneously allowed closure of perineal wounds not amenable to primary closure and transfer of viable tissue into the pelvis to decrease septic and perineal complications [73, 74]. Moreover, myocutaneous flaps may be used to construct a neovagina [75, 76].

Future Directions

The ability to perform radical and extended pelvic cancer surgery is the only potentially curative treatment for patients with locally advanced or recurrent pelvic tumors.

Better diagnostics and chemotherapeutics are likely to be "key" in personalizing

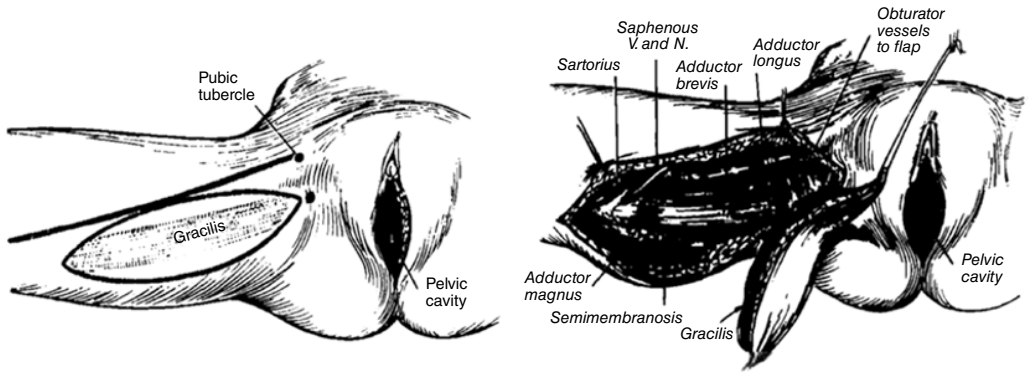

Figure 1.5 Gracilis myocutaneous flap for reconstruction of the perineum after PE as described by McCraw et al. in 1976. Copyright © 1976 Plastic & Reconstructive Surgery. *Source:* Reproduced with permission from Wolters Kluwer [70].

patient care, improving survival, or converting unresectable disease to resectable. In addition, there is growing research on quality-of-life outcome data following extended radical surgery. This is increasingly becoming as important an outcome measure as survival. The PelvEx Collaborative, offers an unique opportunity to prospectively assess exenterative outcomes, refine treatment options and further improve the management of advanced pelvic malignacies.

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2

The Role of the Multidisciplinary Team in the Management of Locally Advanced and Recurrent Rectal Cancer

Dennis P. Schaap[1], Joost Nederend[2], Harm J.T. Rutten[1], and Jacobus W.A. Burger[1]

[1] *Department of Surgery, Catharina Hospital Eindhoven, The Netherlands*
[2] *Department of Radiology, Catharina Hospital Eindhoven, The Netherlands*

Background

Multidisciplinary team meetings (MDTMs) have been implemented to deal with the complexity of cancer care [1]. The aim of these meetings is to provide a structured discussion platform to plan patient care [2–7]. The goal is to benefit from the collective knowledge of all specialties in order to optimize staging, treatment, and follow-up. Furthermore, it can facilitate assessment for patients' inclusion in clinical trials.

The organization of the MDTM is time consuming and comes with costs. Delaying decisions until the MDTM has taken place can sometimes delay treatment. MDTM results in a significant change in diagnosis or treatment planning, ranging from 18.5 to 36% and 11.0 to 14.5% respectively [8–14]. The role of adequate preoperative tumor staging and discussion in an MDTM resulted in more patients receiving neoadjuvant treatment, increased local control, and R0 resections [15].

The governing body for the quality of care for patients with cancer in the Netherlands is the Stichting voor Oncologische Samenwerking (Foundation for Oncological Collaboration, SONCOS) [16]. SONCOS represents 29 national societies involved in cancer care, including the Society for Medical Oncology, the Society of Surgical Oncology, and the Society of Radiation Oncology. SONCOS delivers a yearly report stating the conditions that must be fulfilled by any multidisciplinary team caring for cancer patients. Dutch physicians are obliged to adhere to these conditions. Furthermore, all Dutch medical centers have agreed to standardize data registry with a national database to monitor the effect of changes in treatment strategy on quality measurements as shown in Figure 2.1. Hence, factors improving the quality of care can be identified and applied easily in order to improve patient outcome. MDTMs across the Netherlands can deal with the majority of patients with pelvic cancer from gastroenterological, urological, or gynecological origin. However, patients with locally advanced and recurrent pelvic cancer should be discussed in a specialized MDTM [16].

Complex Pelvic Cancer MDTM

Patients with locally advanced primary and recurrent pelvic cancers are associated with a higher risk of local recurrence, distant

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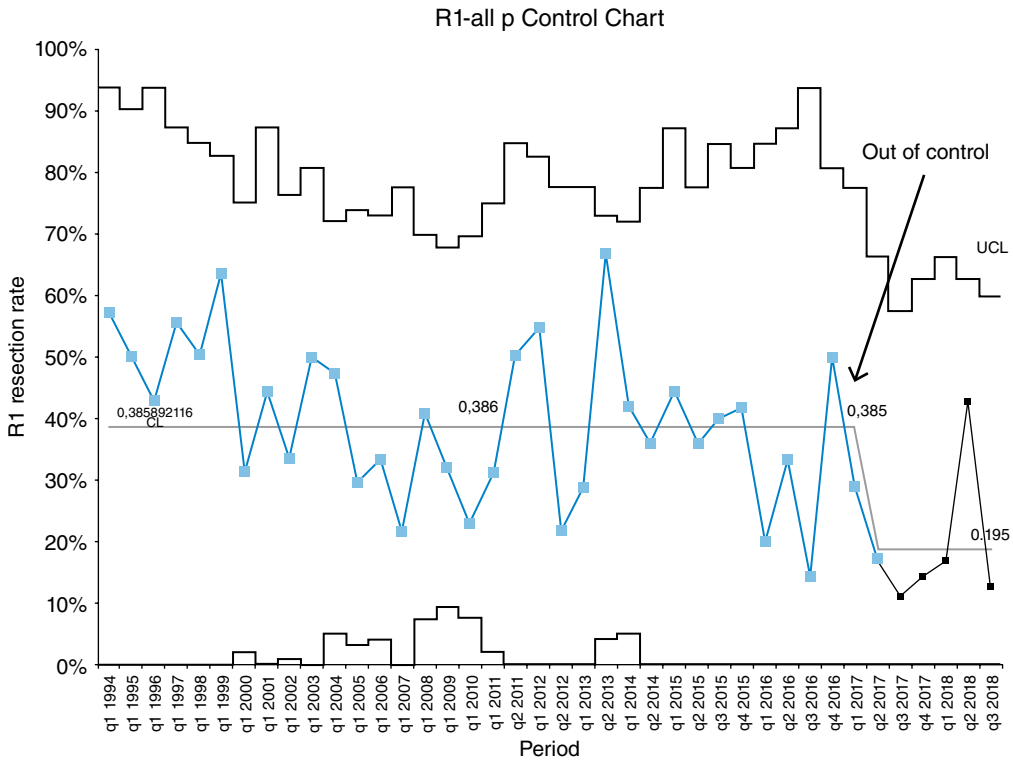

Figure 2.1 National registries help to monitor outcome. In this control chart for proportions, a decrease in R+ resection rate seems to be statistically significant and leads to differences in the mean R+ resection rate. This moment (referred to as 'out of control') coincides with the change of preoperative treatment in locally recurrent pelvic cancer patients (unpublished data). CL, Control limit; UCL, upper control limit.

metastases, and poor survival. Furthermore, these complex pelvic tumors require several specialties for an accurate preoperative evaluation, neoadjuvant and/or adjuvant therapy with a multidisciplinary surgical approach, (Table 2.1). Preoperative treatments providing downstaging are essential to both increase the chance of radical resections and prevent unnecessarily extensive resections that lead to impairment. Centralization is warranted, to identify those patients who require this specialized care.

In order to work toward a situation in which all patients with locally advanced cancers are discussed in a complex cancer MDTM, it is essential that it is easily accessible for physicians outside the specialized center.

Staging, Restaging, and Pathological Assessment

Staging

Radiologic assessment of local and distant disease in the setting of advanced pelvic cancer can be challenging. Therefore all diagnostic imaging is assessed by radiologists and nuclear medicine physicians with specific expertise in cancer imaging prior to the MDTM. An expert radiologist familiar with surgical principles may anticipate the expected organ involvement. Regular contact in the oncological network ensures that referring hospitals know which scan sequences and modalities that are required.

Table 2.1 Differences between hospitals caring for "regular" colorectal cancer patients and hospitals caring for locally advanced and recurrent pelvic cancer patients (Example from The Netherlands).

Regular care for colorectal cancer	Specialized pelvic cancer care
Consultants with special interest in colorectal cancer	Consultants with special interest in locally advanced and pelvic cancer
Two radiologists	Two radiologists with verifiable expertise in evaluation of locally advanced and recurrent pelvic cancer, before and after neoadjuvant treatment
Two surgeons	Two surgeons with verifiable technical expertise in treatment of locally advanced and recurrent pelvic cancer. At least one surgeon with expertise in treatment of stage 4 colorectal cancer
One pathologist	Pathologist with specific expertise in evaluation of specimens of the pelvis and effects of neoadjuvant therapy
One radiation oncologist	Radiation oncologist with expertise in treatment of locally advanced and recurrent pelvic cancer. Expertise in IORT = Intra-operative radiotherapy
One medical oncologist	Medical oncologist with specific expertise in curative treatment of patients with locally advanced and recurrent pelvic cancer
	Extra: Oncological urologist with expertise in urinary deviation
	Extra: Oncological gynecologist with expertise in postoperative care and recovery
	Extra: plastic and reconstructive surgeon with expertise in reconstruction of large oncological defects
24/7 intervention radiology	Experience with acquiring tissue from the pelvis and placing drains in the pelvis, including transgluteal approaches
Stomatherapy nurse clinic	Stomatherapy nurse experienced in care of urinary stoma
protocol for referral for IORT	Provides IORT
MDTM operates according to national guideline	MDTM discusses many patients that cannot be treated according to national guideline
Includes all patients in Dutch Surgical Colorectal Audit (DSCA)	Includes only T4 in audit. Registers all patients in prospective databases, compares with other T4/locally recurrent rectal cancer (LRRC) centers, and publishes results

Restaging

In patients who receive neoadjuvant treatment, response evaluation can be challenging due to the difficulties in distinguishing between malignant and fibrotic changes. Visualizing and assessing complete remission or downsizing of the tumor after neoadjuvant treatment, may alter the surgical planning in highly selected cases the surgical planning. Complete remission after (chemo)radiation cannot be predicted reliably with non-invasive imaging techniques, because of the spatial limitations to detecting microscopic tumor residue [17]. Even magnetic resonance imaging (MRI) can result in false positive predictions. Addition of diffusion-weighted imaging (DWI) to standard MRI makes detection more accurate. Overall, an experienced radiologist with considerable expertise is an essential part of the complex cancer MDTM [18–20].