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National nephrectomy registries: Reviewing the need for population-based data

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Nephrectomy is the cornerstone therapy for renal cell carcinoma (RCC) and continued refinement of the procedure through research may enhance patient outcomes. A national nephrectomy registry may provide the key information needed to assess the procedure at a national level. The aim of this study was to review nephrectomy data available at a population-based level in Australia and to benchmark these data against data from the rest of the world as an examination of the national nephrectomy registry model. A PubMed search identified records pertaining to RCC nephrectomy in Australia. A similar search identified records relating to established nephrectomy registries internationally and other surgical registries of clinical importance. These records were reviewed to address the stated aims of this article. Population-based data within Australia for nephrectomy were lacking. Key issues identified were the difficulty in benchmarking outcomes and no ongoing monitoring of trends. The care centralization debate, which questions whether small-volume centers provide comparable outcomes to high-volume centers, is ongoing. Patterns of adherence and the effectiveness of existing protocols are uncertain. A review of established international registries demonstrated that the registry model can effectively address issues comparable to those identified in the Australian literature. A national nephrectomy registry could address deficiencies identified in a given nation's nephrectomy field. The model is supported by evidence from international examples and will provide the population-based data needed for studies. Scope exists for possible integration with other registries to develop a more encompassing urological or surgical registry. Need remains for further exploration of the feasibility and practicalities of initiating such a registry including a minimum data set, outcome indicators, and auditing of data.

Keywords: Kidney neoplasms; Nephrectomy; Registries

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INTRODUCTION

Medical and surgical registries play an increasingly important role in modern research [1]. Registries have been used to great effect at both the national and international levels in aiding research, assessing current trends in a field, and helping to guide future practice [2-7]. Depending on a

country's present data availability, a national nephrectomy registry may provide the key information needed to assess procedural outcomes at a national level [3]. This review will use the Australian domain as an example to assess the importance a national nephrectomy registry may hold in providing population-level data.

Kidney cancer is a commonly diagnosed malignancy

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in Australia and internationally, accounting for around 3% of new diagnoses annually [8]. International studies in Canada, the United States, and Europe have demonstrated an increasing incidence in renal cell carcinoma (RCC), with rates having risen by 20% to 30% in recent times [9-11]. In a similar timeframe, the incidence of RCC nearly doubled in Australia [8]. This global rise in incidence is likely due at least in part to the increased use of advanced imaging modalities in screening and diagnosis [9,12,13]. While a majority of diagnoses are made in localized stages of disease, the greatest percentage increase occurred for higher-grade tumors and may indicate potential future ramifications for mortality and morbidity rates [9]. Various management options exist for this progressively prevalent diagnosis with promising emergent therapies including minimally invasive focal ablative procedures and targeted pharmacological agents [14,15]. However, given the lack of long-term outcome data and tumor size restriction for ablative therapies (<4 cm), nephrectomy remains the cornerstone of treatment, with over 80% of cases undergoing surgical resection for localized disease [14,16]. Partial nephrectomy has been widely adopted for the treatment of small, localized disease, whereas radical nephrectomy remains the surgery of choice for larger tumors and debulking procedures [17-20]. Given the prevalent implementation of both radical and partial nephrectomy for their respective indications, both remain important aspects of RCC management.

The better nephrectomy is researched in relation to RCC management, the better patient outcomes may be through delivery of the most clinically beneficial and cost-effective treatment. Regarding assessing the state of the nephrectomy field, key areas of concern are as follows: the patterns of care provided, the quality of care provided, and the existing infrastructure for research. Assessing these factors satisfactorily essentially depends on the availability of high-quality, population-based data [7]. As such, a method of providing data of the caliber required to address these key areas at the state and national levels is needed. A possible approach to addressing any paucity in the nephrectomy literature may be the introduction of a national nephrectomy registry. Australia currently has no such registry and was used as an example to assess the need for high-quality population-level data. Surgical registries of a similar nature relating to nephrectomy were reviewed in an attempt to determine to what extent they have demonstrated success in providing population-based data.

The aim of this study was to examine the national nephrectomy registry model in a country with no current registry. This was done by reviewing nephrectomy data

available at a population-based level in Australia and benchmarking these data against data generated from existing nephrectomy registries.

MATERIALS AND METHODS

1. Published literature search on nephrectomy: Australia

A systematic review of the literature was performed to assess the existing publications on nephrectomy within the Australian domain and to identify possible data access-related shortcomings within the field. The review was performed in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) criteria [21]. The search was conducted by using the literature databases PubMed, OVID, Embase, CINAHL, and Web of Science with use of the terms “nephrectomy,” “partial nephrectomy,” “radical nephrectomy,” and “registry” and “population-based data” (and their MeSH terms and synonyms) related to “cancer” in May 2015. The search was limited to English-language articles published between January 1980 and March 2015. Cascading was used to identify references cited in these articles to identify relevant and significant publications not previously included in the search.

2. Published literature search on nephrectomy registries: Worldwide

A similar systematic search was performed to identify published records relating to established nephrectomy or urological registries and RCC. Again, cited references in these articles helped to identify relevant and significant publications not previously included in the search, including other relevant surgical registries of clinical importance. Note that the articles included from the search of established registries were not exhaustive but included those that addressed aspects identified in the Australian field, not all manuscripts generated by the respective registry or database in relation to nephrectomy. These selected records were reviewed and an assessment of their effectiveness in resolving issues comparable to those identified in the Australian literature was conducted.

RESULTS

1. Published literature search: Australia

After exclusion of duplicate publications and those not within the scope of this review, 41 potentially relevant articles were identified. The full texts of these were

screened for relevance to the review, including discussion of nephrectomy in relation to tumors and the use of Australian data. Importantly, level of evidence, sample size, and study design were not screening criteria, because the review aimed to assess possible deficiencies in the field, which made studies of various strength relevant. As a result of this process, 16 articles were selected and critically assessed to address the stated aims of this review (Fig. 1).

2. Published literature search: Worldwide

The results were most significant surrounding the British Association of Urological Surgeons (BAUS) nephrectomy registry, with 13 final results, and the SEER database (Surveillance, Epidemiology, and End Results, USA, www.seer.cancer.gov), with 61 final results.

DISCUSSION

The cornerstones of optimizing patient outcomes include assessing patterns of care, ensuring the quality of care, and ensuring a platform for coordinated research [7,22]. As stated, this relies on high-quality, population-based data, and without this level of access, it would be difficult to properly explore these key domains. This review aimed to determine to what extent these domains can be assessed with current nephrectomy literature in Australia and whether a clinical registry would aid in furthering the field.

1. Monitoring of regional and nationwide outcome trends

Monitoring of outcome trends is an important aspect of ensuring that the highest quality of care is provided for patients. There is little of note in the literature in terms of perioperative and longer-term outcomes within Australia. Case series published from various centers within Australia typically have small sample sizes and are commonly representative of single institutions or even single surgeon data [23-27]. This therefore makes the assessment of nationwide trends difficult without extensive interplay between multiple institutions. Satasivam et al. [28] demonstrated this by independently collecting nephrectomy data from 6 tertiary referral centers across the state of Victoria, totalling 488 patients from 2005 to 2012. Although that study provides highly valuable information, it does not provide the type of whole-population data that would be ideal, capturing only 15% of the 4,000 nephrectomies performed in this time period [28]. The best example in recent times of population-level data in the Australian literature comes from Ta et al. [16], who captured 499 of 577 eligible nephrectomies (87%) in Victoria in 2009. That study was of extremely high caliber and demonstrated the labor-intensive nature needed at present to acquire the necessary data. Even so, it still only provided outcome information years in retrospect. The fact that there is no ongoing monitoring of nephrectomy outcomes in Australia means that there is little possibility of adjusting practices to account for worrying trends.

Contrastingly, the United Kingdom (UK) has the BAUS

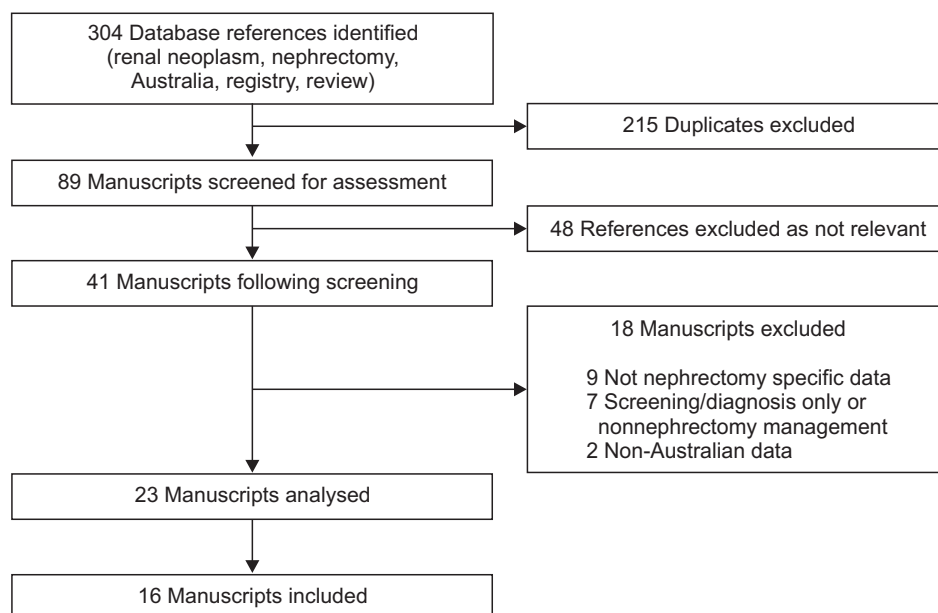


Fig. 1. Identification and screening of Australian nephrectomy publications.

registry to provide data of this nature. In 2012 compulsory reporting by all members of the college focused on nephrectomy with a goal of presenting transparent outcome data in line with governmental (National Health Service) guidelines [3]. This allowed the comparison of current UK nephrectomy outcomes to published series and demonstrated equal or better morbidity and mortality outcomes compared with international standards [3]. Reporting is compulsory, but because BAUS membership is optional, the registry does not capture all nephrectomies performed. However, it is estimated to have covered 91% of nephrectomies (6,805 of 7,478) performed by English urologists in 2013, thus making it one of the best examples of a population-based nephrectomy registry at present.

Similarly, the SEER database in America has collated population-based cancer statistics for essentially all malignancies including RCC. Many articles have been generated examining a wide variety of procedural outcomes from this database with 49 publications generated on RCC nephrectomy in the last 5 years alone. The availability of population-based data gives these studies the capacity to deliver the most accurate outcome measures possible and allows ongoing monitoring of national trends, which is vital for effective and time-sensitive protocol improvement.

2. Benchmarking individual and institutional outcomes

The identification of outcome trends seen in the BAUS and SEER registries has the advantage of delivering a national standard for specific procedures. This allows institutions and individual surgeons to benchmark their own performance outcomes against national and international standards [3]. This is currently not possible within Australia, where the lack of population-based data does not allow for nationally published outcome markers.

A registry would provide these benchmarks in a constantly updating format and would allow centers and individual surgeons to ensure their practices are keeping with the current standard of the field. Centers that do not meet the national benchmark would be given a means of identifying any deficiencies as well as an incentive to rectify them.

Depending on how the regulatory and monitoring protocols of a registry are developed, benchmarking may also provide an opportunity to monitor regional trends that fall significantly below the national standard. This would then provide an opportunity for confidential and nonthreatening investigation of possible discrepancies and allow adjustment of protocols if needed to ensure that the best care is being delivered to patients. Escalating measures would be aimed at

the regional or institutional level to encourage honest and ongoing reporting of data while appropriately responding to identified concerns.

3. Debate over care centralization

Evaluation of studies using Australian data makes it difficult to determine surgeon-specific outcomes because these are not commonly published [16,29]. Assessment of international studies of urological procedures demonstrates marked variability in the number of procedures performed by surgeons and centers [4]. No evidence is available to suggest that similar volume variation does not hold true for nephrectomy performed in Australia. It may be argued that this results in the development of varied proficiency in performing nephrectomies between individual surgeons as well as different institutions. This leads to the debate over a centralization of care protocol. The argument being made is that nephrectomy should only be performed at high-volume centers where experience and subsequent expertise will theoretically be highest. This is a controversial suggestion, because surgeons would be prohibited from performing nephrectomies on the assumed grounds that they have inferior outcomes than their colleagues who carry out nephrectomies more frequently.

BAUS reporting carried out in 2012 made surgeon-specific outcome data available with the intention of evaluating issues such as care centralization [3]. The evidence demonstrated that variation in surgeon procedure volume did not correlate with varied proficiency or diminished outcome measures [3,4]. Morbidity and mortality rates for surgeons were comparable to or better than published standards, thus making the argument against centralization of care [3,4]. Adopting a registry would allow surgeons to demonstrate their proficiency in conducting nephrectomies and dispute care centralization, as was the case in the UK. Additionally, the inclusion of data parameters that facilitate the proper risk stratification of patients would allow fair outcome adjustment to be made for centers that accommodate higher risk cases.

The “learning curve” of training surgeons has been raised as a factor that may lower outcome measures. To account for this, details of surgeon training may be recorded in the registry model. Registries have been used to validate accelerated training programs and may provide a means of refining the teaching process for nephrectomy and help to reduce this learning curve [30].

4. Best practice guidelines

While outside the original scope of this review, best

practice guidelines are an important feature of any field and warrant a brief discussion. Properly developed guidelines require access to the three key domains mentioned to be most effective: patterns of care, quality of care, and a platform for research. Assessing the best practice guidelines in a field relates to their existence, adherence, and effectiveness. For example, despite international organizations developing post-RCC nephrectomy follow-up protocols, no Australian follow-up guidelines currently exist [31-33]. A national registry would aid in the monitoring of follow-up practice as well as the development and refinement of Australian protocols.

Previous international studies have shown marked variability in follow-up frequency with no apparent basis regarding cost-effectiveness or proven clinical benefit [34]. With the side effects and financial strain imposed by radiological imaging (the mainstay of surveillance for this malignancy), it seems pertinent to monitor how clinicians are managing the surveillance of RCC to develop the most clinically beneficial and cost-effective protocol. A registry incorporating upcoming therapies such as pharmacological agents and radio- or cryoablative procedures would allow the monitoring and refinement of guidelines over time to improve patient outcomes. The ability to gather data prospectively and in a highly coordinated manner would provide a substantial platform for ongoing research that is lacking at present.

CONCLUSIONS

A review of nephrectomy literature in a country without a national registry revealed a lack of population-based data. As a result, establishing patterns and quality of care is difficult, as follows:

- Assessment of regional and nationwide outcome trends is difficult to achieve and is often done years in retrospect without ongoing monitoring.
- Difficulty exists in benchmarking individual and institutional outcomes; no national benchmark exists.
- The centralization of care debate cannot be addressed without data on the possible variation in outcomes between low- and high-volume centers.
- Best practice guidelines require data on patterns of adherence and the effectiveness of existing protocols; some protocols require development.
- Limited platforms are available for large-scale prospective studies, thus restricting potential research.

This review suggests that the field of nephrectomy in Australia would benefit from the introduction of new approaches that increase data acquisition and availability,

specifically, prospectively gathering high-quality population-based data. Review of registries that have been established internationally reveals that the registry model can provide these data with possible benefits beyond those discussed in this review. The BAUS and SEER registries demonstrate the merits of the registry model by providing outcome benchmarks for nephrectomy and by ensuring the provision of high-quality care in their respective regions. The regular auditing of data performed by BAUS allows outcome trends to be monitored and appropriate action taken when necessary, allowing any concerning trends to be improved. Individualized outcome data are also available upon request under the BAUS system, giving institutions or even single surgeons the means to benchmark their own practice and adjust accordingly if needed. The large number of publications generated by the respective registries over the past 5 years (57 articles collectively) further reveals the benefit of a registry in providing a platform for generating high-quality research. This demonstrates the potential a national nephrectomy registry holds for allowing countries to benchmark nephrectomy performance and refine the use of the procedure through research.

The development of an integrated registry with contributions made from multiple sources could lead to increased analytical power for countries without access to such data at present. In existing registries, patient data are deidentified and are held by a central body, which is the likely model a newly developed registry would follow. Issues remain around the practicalities of development, logistical management, and governance, but guidance may be taken from the protocols of existing registries in resolving these concerns.

In summary, a centrally held, de-identified nephrectomy registry that collects data for both partial and radical procedures has the potential to enhance the field at a national level. The model is supported by evidence from comparable international examples and will provide the population-based data needed for institutional, regional, and national studies. Future possibilities include the development of a confidential and nonthreatening escalation policy to be implemented should concerning trends in the data emerge. Flexibility and adaption of collected data are important and may allow outcome data for emerging therapies such as ablative and pharmacological agents to be incorporated in the future. Scope exists for amalgamation or interaction with other registries to develop a more encompassing urological or surgical registry. Need remains for further exploration of the feasibility and practicalities of establishing such a registry including a minimum data set, outcome indicators, and auditing processes.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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