



## Evidence-based medicine: an analysis of prophylactic bilateral oophorectomy at time of hysterectomy for benign conditions<sup>a</sup>

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### KEY WORDS

Prophylactic bilateral oophorectomy, incidental bilateral oophorectomy, noncancerous uterine fibroids, hysterectomy

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Sackett *et al.*<sup>1</sup> defined evidence-based medicine as “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.” Prospective randomized clinical trials, through a double-blind process using treatment and control groups, are the optimal method for determining best evidence on interventions used to address a specific medical problem. However, because of economic and ethical issues, it is often not feasible to conduct those types of studies. Short and long-term health outcomes data from diagnostic and treatment protocols applied in actual patients serve as the best substitute.

The management of noncancerous uterine fibroids is central to this research because the standard treatment for abnormal uterine bleeding associated with uterine fibroids is hysterectomy. More than 600,000 hysterectomies are performed annually in the United States as a

direct result of symptomatology associated with uterine fibroids. Of that group, 55% will undergo a prophylactic bilateral oophorectomy at the time of hysterectomy, although fewer than 5% of the patients meet the high-risk criteria for developing ovarian or breast cancer for which the procedure is indicated. Prophylactic interventions, according to Hodges *et al.*<sup>2</sup>, are intended to provide a net benefit to the patient with minimal risk to the patient’s health, in a patient at high risk for developing the disease in the absence of the procedure.

Three hundred thousand women without risk factors for developing ovarian or breast cancer undergo this surgical procedure each year, which raises the question of its medical necessity. Further, if the procedure is performed in the absence of medical necessity, it raises the question of health risks precipitated with its use—the focal point of this dissertation.

Adverse health outcomes experienced after undergoing a hysterectomy and prophylactic bilateral oophorectomy for treatment of noncancerous uterine fibroids was the impetus for this research. The onset of high blood pressure, high cholesterol, pre-diabetes, and weight gain postoperatively, raised questions regarding health risks associated with this prophylactic procedure and whether similar postoperative health outcomes may have been reported by clinicians and researchers conducting outcomes research.

Culiner<sup>3</sup> first raised questions about the use of incidental bilateral oophorectomy at the time of hysterectomy for benign conditions a half-century ago, citing “an endocrine imbalance that cannot be corrected artificially, cardiovascular effects and osteoporosis.” Since the mid-1950s, epidemiologists, public health experts, and gynecologists have made additions to this initial risk profile of an increasingly severe and debilitating nature:

- Colditz *et al.*<sup>4</sup> reported a higher incidence of coronary vascular disease.
- Shoupe<sup>5</sup> reported a higher incidence of dementia, depressive, and mood disorders; a higher incidence of coronary vascular disease; and a higher incidence of sexual dysfunction.

<sup>a</sup> Diagnostic and treatment algorithms and a proprietary over-the-counter (OTC) product and treatment regimen were developed that resolved the adverse health outcomes precipitated by this surgical procedure. Commercialization efforts are underway to bring this proprietary OTC product and treatment regimen to other consumers who have experienced similar postoperative health outcomes after undergoing this surgical procedure.

*Alternative Medicine* (2007), the author’s first publication, introduced the concept of evidence-based medicine to the U.S. consumer by exploring the science underlying both alternative and conventional medicine, with issues to consider in its absence. Medical reviews and endorsements on preliminary research in evidence-based medicine can be accessed at the company website: [www.savvyconsumerguidetohealthcare.com](http://www.savvyconsumerguidetohealthcare.com).

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- Parker *et al.*<sup>6</sup> reported a higher incidence of heart disease, cancer, stroke, all-cause mortality, and premature death.
- Rocca *et al.*<sup>7–11</sup> reported a higher incidence of cognitive decline, dementia, and Parkinson disease, and a higher incidence of anxiety, depressive, and psychiatric disorders.
- Schuster *et al.*<sup>12</sup> reported a higher incidence of all-cause mortality and a higher incidence of premature death.

Rather than the adverse health outcomes experienced postoperatively being an “N of 1,” the foregoing dissertation research findings indicate that these outcomes, may in fact, be a prototype for many women who undergo this surgical procedure. “Why have rates of incidental bilateral oophorectomy in women without risk factors remained at 50% since the late 1980s, in spite of the growing body of scientific evidence that documents severe and debilitating health consequences, up to and including premature death, reported with its use?” was the research question that drove this dissertation.

In academic health centers across the United States, 35 obstetrician–gynecologists were interviewed in this qualitative research study—10 in phase I and 25 in phase IV—to more fully understand clinical decision-making and evidence-based support for the use of incidental bilateral oophorectomy in women without risk factors. The Centers for Disease Control and Prevention and the American College of Obstetricians and Gynecologists (ACOG) were both included to be interviewed in the original research design, but declined to participate.

Issues of critical importance in this dissertation research include

- when incidental bilateral oophorectomy in women without risk factors was first introduced.
- the scientific basis for the procedure’s use in women without risk factors.
- why and how its use in women without risk factors became widespread.
- when adverse health consequences associated with this procedure first appeared in the literature.
- the severity of adverse health consequences reported in the literature over time.
- the response of specialists to these scientific publications.
- the role of ACOG practice guidelines in the use of this procedure in women without risk factors.

De-identification protocols were used for subjects and institutions interviewed, with one exception: William Parker MD, who requested to remain public. De-identification protocols with Parker were particularly difficult, in large part because of the release of

his study results, which were publicized on the *CBS Evening News* with Katie Couric, WebMD ([www.webmd.com/](http://www.webmd.com/)), and *The New York Times* during the final phase of research. Although subjects in the Parker *et al.* study<sup>14</sup> had a *decreased* risk for breast or ovarian cancer, their risk for all-cause mortality, for both fatal and nonfatal coronary artery disease, and lung cancer *increased*.

These dissertation research findings indicate that, for more than 35 years, prophylactic bilateral oophorectomy in women without risk factors, widely assumed to be life-enhancing, has for many women been inducing a wide variety of chronic disabling conditions and causing premature death. These results have occurred unbeknownst to many of the specialists performing the procedure and to many of the patients who consented to it.

The dissertation provides an explanation for this phenomenon and for the institutional and behavioural factors that have contributed to the persistence of this surgical procedure’s use in women without risk factors. It is considered to be the first scientific analysis of this surgical procedure conducted by a former patient.

## CONFLICT OF INTEREST DISCLOSURES

The author reports no financial conflicts of interest.

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