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Does Metal-on-Metal Total Hip Prosthesis have Influence on Cancer? A long-term follow-up study

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Introduction

Patients with metal-on-metal McKee-Farrar total hip arthroplasty (THA) [25] have had significant elevations of chromium, and cobalt in their body fluids [19]. Patients with modern metal-on-metal hip prostheses produce serum cobalt levels, which are significantly higher from those of the ceramic-on-polyethylene group [6]. Release of metal ions from metal-metal bearings leads to a significantly elevated cobalt and chromium concentrations in blood and urine [33]. Elevated cobalt levels in serum of patients with metal-on-metal prosthesis seem to correlate with physical activity of the patients [14]. Patients with a hip or knee endoprosthesis have a widespread dissemination of metal particles especially in para-aortic lymph nodes, liver, spleen, and bone marrow [7, 39].

According to IARC classifications implanted foreign bodies of metallic cobalt, metallic nickel and a particular alloy powder consisting of 66-67% nickel, 13-16% chromium and 7% iron are classified as possible carcinogenic to humans (group 2B) [16]. Orthopedic implants of complex composition were not classifiable as to their carcinogenicity to humans (Group 3) [16]. Hexavalent chromium and nickel oxides and sulfides are established carcinogens (Group 1), i.e. there is sufficient evidence that these compounds can cause respiratory tract cancer when inhaled [5].

Patients with metal-metal bearings are thus continuously exposed to metal particles and ions

released from the prosthesis. Modern metal-on-metal prostheses have gained a wide acceptance [9, 34, 40]. Because these prostheses are estimated to last for 30 years, long-term studies are needed to determine the risk of metal-on-metal implants as a potential cause of cancer. We updated a series of McKee-Farrar patients with a maximum follow-up time of 30 years and analyzed their risk of cancer.

Material and methods

The basic material comprised of 698 McKee-Farrar patients who had undergone a THA between 1967-73 at the Orthopedic Hospital of the Invalid Foundation or at the Department of Orthopedics and Traumatology, Central University Hospital, Helsinki, Finland. When the other diagnoses than primary osteoarthritis were excluded, the studied series consisted of 579 metal-on-metal patients. The proportion of women was 66% (Tab. 1).

All persons in Finland are identified since first of January 1967 with a unique 11-digit personal identifier (PID). The PID is composed of day of birth, month, year, a symbol indicating the century of birth and a running registration number (three digits) and a check digit. Dates of death and emigration were obtained from the Central Statistical Office of Finland with the help of PID. Follow-up of cancer through the files of the population based country-wide Finnish Cancer

Table 1: Number of person years by time since operation (follow-up years) and gender.

Follow-up	Males (N: 198)	Females (N: 381)	Total (N: 579)
0– 4.9	919	1858	2777
5–14.9	1332	3034	4366
15+	681	1933	2613
Total	2931	6825	9756

Registry was also done automatically. The follow-up for cancer started at the date of THA and ended at emigration, at death, or on December 31, 1997, whichever occurred first. There were no losses in the follow-up. The average follow-up time was 16.8 years and in 27% the follow-up time was more than 15 years after surgery.

The number of observed cases and person-years at risk were counted as groups for 0–4, 5–14 and over 15 years of follow-up periods, separately. (Tab. 1) The number of person-years at risk for was 9756 years.

The expected numbers of cases for total cancer and for specific cancer types were calculated by sex and by 5-year age group by multiplying the number of person-years in each stratum by the corresponding average cancer incidence in whole Finland during the period of observation. Further division was made by the time elapsed since operation using one and five years' intervals up to 28 years. The specific cancer types a priori selected for the analysis included cancer sites with suspected exceptional risks among THA patients in earlier studies, and the other common cancer types to give the whole picture of cancer situation in THA patients [28, 41, 42].

To calculate the standardized incidence ratio (SIR), the observed number of cases was divided by the expected number. Exact 95% confidence intervals (CI) were defined, on the presumption that the number of observed cases followed a Poisson distribution.

Results

Total number of the observed cancers was 134 and that of the expected 130.4 (Tab. 2). The SIR was 1.00 (0.7–1.5) during the first 5 follow-up years since THA, 1.0 (0.8–1.3) during the following 10 years and 1.0 (0.8–1.4) after 15 years of follow-up, respectively. Annual incidence of all site cancer followed quite exactly with that of general population (Fig. 1). After 10th. year of follow-up male patients had less and after 5th. years female patients more cancers than expected (Figs. 2–3), but the differences were not significant. The SIR for men after 15th year of follow-up was 0.8 (0.5–1.4) and for females 1.2 (0.8–1.6).

Lung cancer incidence was decreased throughout the whole follow-up time especially among male patients (SIR 0.5, 0.2–0.9). For males the corresponding figures were 0.8 (0.2–2.2) during the first 5 postoperative years, 0.5 (0.1–1.4) between 5–15 years and 0.3 (0.0–1.9) thereafter. For females the corresponding figures were 0.5 (0.0–6.8), 1.4 (0.0–3.9) and 1.3 (0.0–2.8) respectively.

There was a significant excess for cancer with unknown primary site among females, (SIR 2.8, 1.2–5.4), but not among males (SIR 0.9, 0.0–4.9).

There was borderline significant excess of colon cancer after 15 years of follow-up. The SIR was 3.4 (1.0–4.6). Total number of observed haematopoietic cancers was 12 and that of expected 8.4 (SIR 1.4, 0.7–2.5). Incidence of leukaemia was significantly, increased only during the follow-up years of 5–14, SIR 3.2 (1.0–7.4).

Table 2: Observed (Obs) and expected (Exp) numbers of cancer cases and standardized incidence ratios (SIRs) with 95% confidence intervals (95% CI) in 579 McKee-Farrar patients followed from the date of first hip replacement from 1967 to the end of 1997.

Primary site	Obs	Exp	SIR	95%CI
All sites	134	130.4	1.0	0.9– 1.2
Stomach	9	11.9	0.8	0.4– 1.4
Colon	11	8.4	1.3	0.7– 2.4
Rectum	7	5.9	1.2	0.5– 2.5
Liver	2	1.9	1.1	0.1– 3.8
Gallbladder	4	2.8	1.4	0.4– 3.6
Pancreas	9	6.2	1.5	0.7– 2.7
Larynx	1	0.8	1.2	0.0– 6.6
Lung	8	16.7	0.5	0.2– 0.9
Breast	14	13.7	1.0	0.6– 1.7
Uterus, cervix	–	1.5	0.0	0.0– 2.4
Uterus, corpus	7	3.5	2.0	0.8– 4.2
Ovary	1	3.0	0.3	0.0– 1.9
Prostate	15	9.9	1.5	0.9– 2.5
Kidney	3	3.7	0.8	0.2– 2.4
Bladder, ureter, urethra	1	4.9	0.2	0.0– 1.1
Melanoma	2	1.9	1.1	0.1– 3.9
Skin ¹⁾	4	5.1	0.8	0.2– 2.0
Brain/nerves	2	2.3	0.7	0.1– 3.1
Thyroid	1	1.2	0.9	0.0– 4.8
Bone	–	0.2	0.0	0.0–19.2
Connective tissue	–	0.7	0.0	0.0– 5.5
Non Hodgkin lymphoma	1	2.5	0.8	0.1– 2.9
Hodgkin lymphoma	1	0.5	2.1	0.1–11.7
Myeloma	3	2.1	1.4	0.3– 4.1
Leukemia	7	3.3	2.1	0.9– 4.3
Undefined cancer	9	4.0	2.2	1.0– 4.2

¹⁾ Basalioma excluded

A slight decrease of urinary tract cancers was observed: (SIR 0.5, 0.1–1.2). No case of bone or connective tissue sarcoma was found. As a whole the other forms of cancer were in concordance with general population (Tab. 2).

Discussion

Osteoarthritis was chosen for the preoperative diagnosis, because it has not been known to be related to cancer [23, 38].

When the patients with metal-on-metal prostheses are exposed to metal ions and particles for long periods, an increase of cancer incidence might be expected. In the present series the ex-

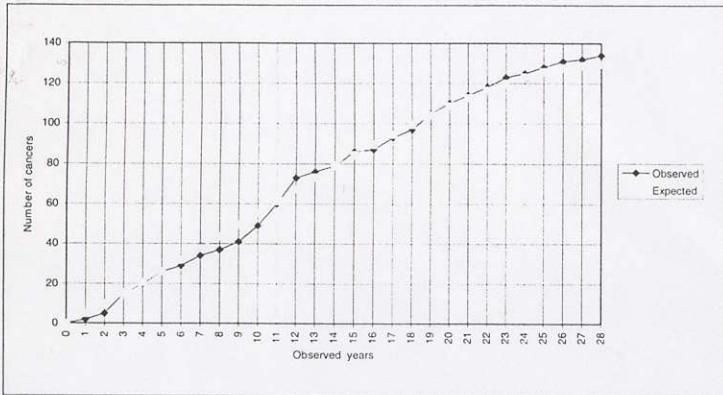


Figure 1: Cumulative number of observed and expected cancer cases among patients with metal-on-metal total hip arthroplasty, by time since THA.

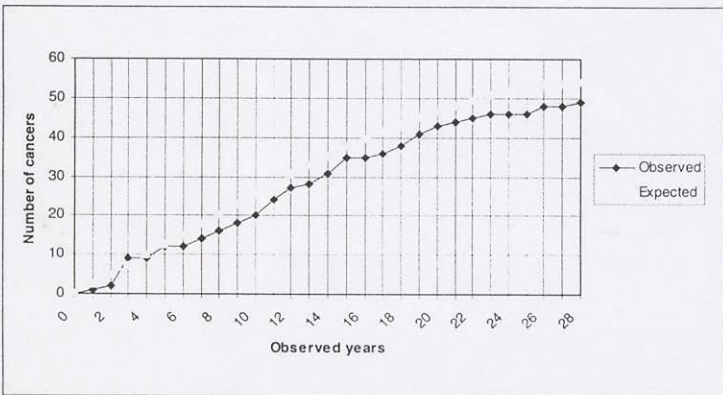


Figure 2: Cumulative number of observed and expected cancer cases among male patients with metal-on-metal total hip arthroplasty, by time since THA.

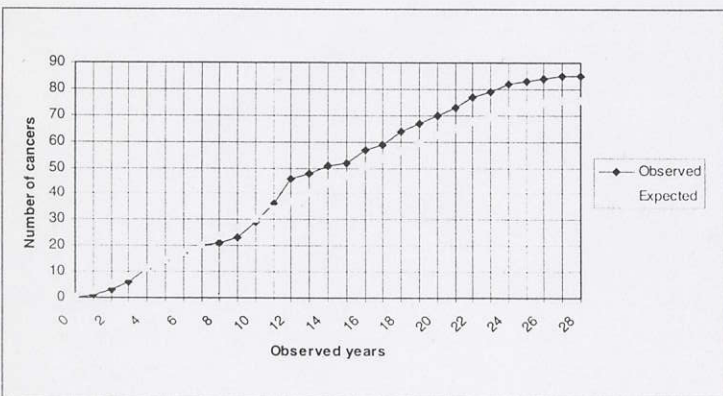


Figure 3: Cumulative number of observed and expected cancer cases among female patients with metal-on-metal total hip arthroplasty, by time since THA.

cess was only three per cent. Correspondingly a three per cent excess of total cancer was observed in a large Swedish cohort [26], but that series also included patients operated on for late or acute fracture, for rheumatoid arthritis and for other causes than osteoarthritis. Most THA series with a diagnosis of primary osteoarthritis show a decreased incidence of all site cancer [27, 28, 41].

Each Nordic country has a population based cancer registry with a close to 100% coverage [37], which enables high accuracy nation-wide analytical studies on cancer risk of large populations with THAs [26, 27, 28, 41, 42]. Two of these cohorts showed a significant decrease of all site cancer [27, 28]. Our cohort had a higher incidence of total cancer than these two series. These cohorts are, however, cannot be compared, because the patients with McKee-Farrar prostheses were the first to be implanted in Finland and their general health would differ from that of later series. Corresponding general population is the only criterion for comparison.

Preoperative selection of the patients ensures that the patients do not have any severe illnesses. THA and TKA patients operated for primary osteoarthritis have a longer life expectancy than general population [11, 15, 30, 44] "Healthy patient effect", which in this case is probably attributable to favorable life habits, has been used to explain the total reduction of cancer incidence among THA patients [42]. In the present cohort this effect was seen during the first about 10 years after THA. After that the cancer incidence in the cohort reached that of the general population.

From the site specific cancers local sarcoma, hematopoietic cancers and urinary tract cancers are of special interest, because wear and corrosion products from the prosthesis burden especially hematopoietic and urinary tract organs.

The 10-year survivorship of the first 511 McKee-Farrar prostheses of the present series was 76%, including thus a high number of loosened prostheses [43]. Failure of the prosthesis produces high concentrations of metallic compounds and particles around the prosthesis and distant organs [3, 4, 17, 39].

Between 1974–84 only four cases of local

sarcoma at the site of the metal-on-metal hip prosthesis have been reported: two osteosarcomas [32, 36] one fibrosarcoma [2] and one malignant fibrous histiocytoma [29]. The first reported case was operated on for postradiation necrosis of the femoral head and the local osteosarcoma developed only 6 months after surgery [32]. The mean latent period for the sarcoma of these cases was only 2.9 (0.5–5.0) years. The corresponding figure was 6.3 (0.5–15) years for 29 patients with polyethylene-on metal prostheses [16, 18, 35]. Despite large number of the modern metal-on-metal prosthesis no case of local sarcoma has been reported. Development of local sarcoma at the site of the prosthesis is most probably coincidental.

The early observations suggested that THA carries an increased risk for hematopoietic cancers [12, 42]. Long-term exposure to the metallic ions could be expected to increase this risk. Higher chromosomal aberrations were found in the lymphocytes adjacent to the prosthesis than in cells from the iliac crest indicating premalignant changes of these cells [8]. However, the SIR of leukemia and lymphomas in association of the McKee-Farrar prosthesis was reduced from 3.0 (1.1–6.6) in the earlier cohort [42] to 1.4 (0.7–2.5) in the present cohort. Both cohorts included in part the same patients, but in the earlier cohort there were patients with rheumatoid arthritis and postraumatic osteoarthritis. In a Swedish series [24] the risk of lymphoma and leukaemia was also increased (SIR 2.7, 1.5–4.4) during the first year after surgery but was in concordance thereafter. Gillespie et al. [13] could not confirm an increased risk of hematopoietic cancers in his cohort and in a case control studies of THA and TKA patients.

Stress and finally depletion of the immune system by the extensive amounts of the wear and corrosion products from the prosthesis has been considered to promote tumor growth among patients with endoprostheses [10]. In general major changes in immune function are associated with a markedly increases risk of non-Hodgkin's lymphoma [22]. No excess cases of non-Hodgkin's lymphoma were found in this cohort.

Nyren et al. [26] reported an increased risk of the renal cancer (SIR 1.3, 1.1–1.5), but this increase could not be observed in the present cohort or in other cohorts including only osteoarthritic patients [27, 28, 41]. The burden produced by metallic ions does not seem to promote malignant degeneration of the urinary tract.

Increase of unspecified cancer of the present cohort was bound to female gender and the origin of this tumor could thus be gynecological.

Most of the THA cohorts including the present series show a significant deficit risk of lung cancer [27, 28, 41]. Less smoking of the prosthesis carriers compared to general population is perhaps the major reason for this observation. Recently a serological association was found between *Chlamydia pneumoniae* infection and lung cancer [20, 21]. THA and TKA patients are easily treated with antibiotics for respiratory tract and other infections to prevent hematogenous spread of the bacteria to the prosthesis. These antibiotics may control *Chlamydia* infections.

Reduced cancer mortality after a mean follow-up of 12 years was seen in a Finnish series of 1081 metal-on-metal and metal-on-polyethylene THA patients (0.77, 95% CI 0.59–0.99) [45]. There were 6 cancer deaths among 237 metal-on-metal and 27 among 781 polyethylene-on-metal THA patients; relative risk being 0.71 among age and sex matched patients during ten years of follow-up. Calculated cancer mortality per 10000 person years was 27.5 for metal-on-metal and 39.0 for metal-on-polyethylene THA patients [45]. This is one cause for the extended life expectancy of THA patients.

A latency period exceeding 20 years was needed to state the increased risk of lung cancer among refinery workers exposed to nickel sulfate [1]. Lung cancer mortality of former chromium smelter workers increased with increasing duration of employment and latency since time of first employment [31]. Contrary to the observations in metal industry long term exposure to metals from metal-on-metal bearings is well tolerated in the respect to cancer risks by the ordinary, elderly THA population.

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