Introduction

Penile cancer, while fairly rare, is devastating to those afflicted with it. Many claim that having an intact foreskin (being not circumcised) increases one's risk of acquiring this disease. Is this really the case or is this due to a bias in the literature here in the United States?

Circumcision is so common here in the United States that many health care providers and parents are unfamiliar with proper care methods for the intact penis. Many parents are advised that they should be retracting their sons from a very young age and washing under the foreskin with soap. This creates trauma to the foreskin including many small tears and abrasions that can lead to a buildup of scar tissue. This can cause phimosis which is an inability to retract the foreskin. This exposure and washing with soap can cause infections and because it is a sensitive area of the body the soap can cause chronic irritation.

Phimosis, chronic irritation, and penile trauma of cuts and abrasions are all listed as some of the prominent risk factors associated with penile cancer [1-5]. There is much controversy concerning the practice of circumcision with many believing that it prevents penile cancer [6-7]. However, these risk factors the literature mentions (phimosis, penile trauma, and chronic irritation) are all something that can be caused by improper care of the intact penis. Is the risk truly from having an intact foreskin or is it from the mistreatment of it? If it is truly mistreatment of the intact penis that causes this risk rather than the foreskin itself might not proper education change the American outlook on the practice of circumcision and their perceptions of the foreskin?
Literature Review

Throughout the literature, there seems to be recurring themes of the risk factors for penile cancer. These include HPV, smoking, phimosis, the number of sexual partners, penile hygiene, chronic irritation, and penile trauma consisting of cuts, tears, and abrasions. They come to the conclusion that circumcision will reduce the risk. This study will focus on those factors having to do with hygiene and care of the intact penis and try to establish a link between the methods of care often used versus those who do not utilize these methods.

In a paper by Christodoulidou et al., HPV and phimosis are identified as the most important risk factors [8]. HPV appears to be associated with penile cancer nearly half the time. They note that “phimosis was found in approximately 60% of their cohort” [8]. They mention that penile hygiene is a recurring theme throughout the literature. This might partly explain why the rates of penile cancer are higher in less developed countries. Increased hygiene alone appears to significantly reduce penile cancer incidence. They say that “in a Danish case series where the rate of circumcision is only 1.6%, a decreased incidence in penile cancer was observed from 1.15-0.82 per 100,000 solely owing to improved hygiene” [8].

Another article by Breen et al., [9] looks at the patient history and treatment methods of 25 patients that were treated at a facility in Ireland. Of these patients, 40% had a history of phimosis. The article mentions that other known risks include poor hygiene, smoking, and HPV. They also mentioned that three of the men had been circumcised as adults, two being for phimosis and one for Balanitis Xerotica Obliterans. These two things seem to indicate that many of these men did indeed have a history of these risk factors.

Since there is little literature on the effects of forced retraction and soap on the male genitals, it is necessary to look to literature from other disciplines. Stretching the foreskin or any skin of the body leaves it irritated and sore. Forced retraction rips the foreskin apart from the glans over and over again, causing trauma that can often leads to bleeding. In an article on preventing improper care, Bollinger (2007) says that “Premature Forced Foreskin Retraction (PFFR) is essentially being skinned alive” [10]. If stretched too far, there will be pain and micro tears. For the effects of soap, there is a whole host of dermatology literature that documents this, though not for the genitals. One article in particular by Ali and Yosipovitch (2013) recounts a very good example of soap effects for acne:

Often, patients with intertrigo or acne, believing that their dermatoses are related to poor hygiene, overuse harsh soaps exacerbating the condition and a vicious cycle of further cleansing ensues. Proper education and recommendations on appropriate topicals is crucial in these situations [11].

This same effect on the genitals would be considered chronic irritation and definitely be a trauma to the skin in this area.

In another dermatology article Williams et al., look at the irritation caused by soaps for hand washing [12]. They state that “the results from phase 2 of our study confirm the work of previous studies that show that regular exposure to irritants in daily life leads to stratum corneum damage and impairment of the skin barrier” [12]. These dermatology articles taken as a whole are very definite that soap damages the skin and that frequent soap use causes breakdown of the skin. This is another source of trauma.

Birley et al., link the use of soaps and excessive cleaning to various skin issues including Balanitis [13]. In speaking of Non-Specific Dermatitis (NSD), which is definitely an ongoing skin irritation issue, they state that “a history of fluctuating episodes, with a rapid onset, as well as that of atopy and of zealous washing were predictive of a histological diagnosis of NSD” [13]. In concluding the study, they say that “the experience we have gained from this series suggests that an empirical trial of emollient creams combined with advice to reduce frequent washing with soap is an appropriate first line management for patients with recurrent Balanitis” [13]. While this is not recent research, it is important to include because it does show a link between the use of soap and chronic irritating skin conditions. The date of this research also highlights the fact that nothing has been done to further explore this line of research in the past 23 years, making it all the more urgent that a causal link be further explored. It is also in line with the more recent dermatology articles illustrating the link of soap with skin irritation.

It is necessary to look into the methods of care intact men have received or performed from infancy until diagnosis of cancer to determine if the care received has any relationship with the risk factors for penile cancer. No one has asked the questions intended to be asked because they believe that circumcision is the solution. Not only does this idea have multiple problems with it, but other countries don't see a drastic increase in incidence despite being largely intact. The difference in care is the key because in the United States most people, including many medical professionals, have no experience with foreskin. Many in medical school learn nothing about it except how to cut it off. As a direct result of ignorance and incorrect information, direct harm occurs. The goal is to see if the following of this incorrect information leads to an increased risk. Does incorrect care of the foreskin lead to increased risk of penile cancer or not? This is the question that needs to be researched and to this end, the following research study would be of great benefit.

Research Design and Methods

Research design: This project will be a study utilizing primarily qualitative information. The goal is to establish a link between the manners of past care of the intact penis in order to see if there is a correlation with the subject's current diagnosis of penile cancer. Patient medical records will be used but due to shortcomings in using records not designed to answer certain
questions, a specific questionnaire will also be designed. This detailed questionnaire will be given to all participants asking about each of the independent variables. The responses would then be categorized according to the way they were answered and analyzed for how the answers correlated with having penile cancer and how many risk factors, the severity or extent of risk factors and so on. The circumcision status of each participant will also be recorded and the age of circumcision if applicable. It will be a Retrospective Cohort Study because it will use information from practices that have occurred in the past. It is the perfect study design for looking at certain behaviors or practices and seeing if they lead to a certain outcome.

The dependent variable in this study is a diagnosis of penile cancer. There are several independent variables. The first independent variable is forced retraction. Forced retraction would be indicative of the risk factors of penile trauma of cuts and abrasions. It would also be noted whether it has never happened, happened once or twice, a few times, or regularly. Another variable will be if there has been a history of phimosis. Another variable will be the hygiene method the subject has employed throughout life. The final independent variable will be whether there have been periods of penile irritation in this area and the frequency.

The possibility of a prospective cohort arm that would look at a similar group of men and note their method of care of the penis and their histories and observe them longitudinally to see if a greater percentage of those who followed incorrect care practices acquired penile cancer was considered. This arm was ultimately rejected for several reasons. The number of cases diagnosed each year is so small that an extremely large cohort would have to be followed over a very long time period, and there is no guarantee that any of them would ever acquire penile cancer. According to Lawindy et al., the number of new cases in the United States for 2010 was 1,250 [14]. There is also the consideration that ethically one would have to inform the subjects that their current practice potentially increases the risk of penile cancer, and this could very likely create a change in their practices and thus make the results unclear.

**Definition of variables:**

1) **Forced Retraction** - Pulling back the foreskin and exposing the glans penis by anyone other than the subject himself of his own volition for any reason from infancy until such time as the subject considers himself easily retractable.

2) **History of Phimosis** - An inability to retract the foreskin or only with great difficulty after the age of 18. This age is selected because phimosis is often confused with the normal inability to retract of young intact boys due to the misunderstanding of the physiological process involved but this process is normally complete by this age.

3) **Hygiene Method** - For this study means whether soap was used inside the foreskin and on the glans, water only, or nothing.

4) **Penile Irritation** - Here defined to mean periods of redness and/or itching on the glans and under the foreskin that has persisted for 3 or more days at a time.

5) **Circumcised** - Male who has undergone surgery to remove the foreskin from his penis.

6) **Intact** - Male who has had none of his foreskin removed and often referred to as uncircumcised.

**Sample**

The cohort selected will be 200 men of any age. The only requirement will be that they are male and have a verified diagnosis of penile cancer from a certified physician. A region in the Midwest consisting of Illinois, Indiana, Ohio, and Michigan has been defined as the area. After obtaining appropriate IRB approval, a list of cancer centers in this region will be compiled. Each cancer center will be contacted and requested to provide a list of all patients still living that have a diagnosis of penile cancer from the past five years and their contact information. The cohort to be selected is appropriate since the purpose of the study is to see if the manner of care of the penis and foreskin or the medical history of this body part is in any way linked to the present diagnosis which is the one thing that all subjects of the population will have in common. Since it is a retrospective study, there are no expected benefits to the cohort selected except the satisfaction of knowing that they are helping to advance knowledge and perhaps save other men from going through what they are going through.

**Instruments/Measurement/Procedures**

Data collection will be a one-time event and will not be on-going. The primary researcher will create the questionnaire and mail it to the home address of each subject, including a letter stating the purpose of the study and requesting their participation. There will also be a stamped return envelope filled out with the address of the study headquarters. The participant will be requested to respond to all questions and put it back in the mail. It is likely that many of those selected will never fill out the questionnaire, so to correct this expected attrition those who do not respond will be contacted by phone. If consent is obtained, the questionnaire will be done verbally over the phone with the researcher recording the responses. If the subject declines, they will not be contacted further. For the questionnaire responses obtained by phone, the researcher will record the information on the questionnaire as if the subject is filling it out. When 200 questionnaires are obtained, either by phone or returned in the mail, no further questionnaires will be added.

Each subject will be asked (question 1) if they are circumcised or intact and the age of circumcision if applicable. This will be defined for them. They will be asked (question 2) if they have ever experienced forced retraction, and this will be defined. Responses will be: never, once or twice, a few times, and regularly. They will be asked (question 3) if they have a
Each question will be depicted by its own graph. For Methods of Analysis

The data will then be entered from the questionnaires using a standard desktop computer that has Microsoft Office Excel 2010. Data will be manually entered by keyboard from the questionnaires into Excel spreadsheets with all categories appropriately labeled. The data will be entered into a second Excel spreadsheet, and the two files will be compared to ensure accurate data entry.

**Methods of Analysis**

Each question will be depicted by its own graph. For question 1 the distribution will be shown by means of a pie chart. Question 3 will also be depicted by a pie chart. A simple frequency distribution bar chart. Question 1 the distribution will be shown by means of a pie chart. Question 2 will be depicted by a bar chart. The X axis will be the number of participants, and the Y axis will be the numerical values of that answer. The mean will be determined by summing the values for each category (questions 2, 4, and 5) and divided by the number of participants to figure out the central tendency. The standard deviation will be calculated using this equation:

$$S = \sqrt{\frac{\sum (X - \bar{X})^2}{n - 1}}$$

The standard deviation will be useful by showing the spread of the scores around the average. This will help determine if there is a trend in certain behaviors or the prevalence of the various behaviors denoted.

Since the purpose of the study is to see if each variable is related to a diagnosis of penile cancer, the correlation for each variable will be calculated to see the degree of relationship:

$$r = \frac{n(\Sigma xy) - (\Sigma x)(\Sigma y)}{\sqrt{[n\Sigma x^2 - (\Sigma x)^2][n\Sigma y^2 - (\Sigma y)^2]}}$$

This will be crucial in determining if there is a relationship between the various behaviors and the risk of penile cancer and if it is a strong or weak relationship.

**Discussion**

This study is looking to establish correlation. It is expected that there will be a strong correlation between each variable and the risk of penile cancer. While correlation is not causation, the stronger the correlation, the more confidence one could have in creating a further research study to investigate a causal relationship. It will also be important to see which variables are the most strongly correlated and if the results will, in fact, justify changes in genitourinary medical practice, such as ceasing the practice of circumcision and implementing an educational program to instruct in the proper care of the intact penis. This correlational study will be the first step in the process.

The current literature always mentions the same list of risk factors but they never indicate the history of the patient with regard to penile trauma of any sort, forced retraction, use of soap and chronic irritation. A history of phimosis is the only thing they ever seem to mention. It will be important to look into this list of risk factors to see how many patients have them, but more importantly, to look deeper and see the sort of care they received and the hygiene methods they have employed in order to see if this is what actually caused the risk factors in the first place. Currently the literature seems to take for granted that a foreskin increases risk rather than investigating the root causes of the risk factors. This is not a valid assumption to make without further research. Many of the things that are mentioned as risks are themselves often the direct result of improper care. Additional research demonstrating that all of these health issues could be fixed by simple instructions on proper care rather than traumatic surgery early in life could affect healthcare standards. This could help the entire health system by simultaneously reducing unnecessary surgery and preventing the common issues that are currently considered the inevitable alternative as shown in previous research conducted [15]. If this manner of forced retraction and washing with soap are the true causes of this increased risk, then it is imperative that correct information be written up and disseminated quickly and accurately to physicians and to medical schools so that these medical professionals can learn the correct methods and spread this information to their patients. Future work could build on this by creating an educational program to explain not only proper care but also the benefits of remaining intact.

**Conclusion**

A thorough review of the literature produces a fairly set list of risk factors for penile cancer. What remains to be established conclusively is whether these risk factors are present because one has an intact foreskin or if the improper care of the intact foreskin is creating the problem. Studies establishing correlation and then causation could have a far-reaching
impact on American medicine. It could lead to better education for both medical practitioners and lay people alike regarding proper intact care. As we enter a new era of trying to reign in on unnecessary procedures it could also help to bring the country more in line with Europe where the practice is already quite rare and yet have no increase in foreskin-related diseases. This is an area of research where not much has been done and it is vital that we not ignore the root causes of these risk factors.

References