

# Patient Input Requested to Help Develop a U.K. Clinical Trial for Low Risk, Recurrent Bladder Cancer

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Stage Ta, grade 1, single papillary tumor, <3cm; Papillary neoplasm of low malignant potential (PNLMP)

Experts around the world agree that a large subset of bladder tumors carry virtually no risk of progression, although recurrence is very common. When the diagnosis is bladder cancer, regular follow-up is recommended for life. In case of low-risk bladder cancer, repeated cystoscopies and surgical removal can do more harm than good over the long-term. Many people dealing with bladder cancer are elderly, with co-morbidities that may make anesthesia difficult or even dangerous. Over-treatment is a great concern for this population, bringing with it short and long-term risks and complications that could be avoided with less aggressive approaches. Even cystoscopy has its risks, such as infection and long term wear and tear that can often lead to incontinence after years of follow-up.

Numerous studies have reported that these low-risk recurrences sometimes disappear with expectant treatment, also known as 'watchful waiting'. Other studies have shown that using a course of intravesical chemo - known as 'chemo-resection' - is effective at eradicating recurrences and may be better in many cases than subjecting patients to the risks of repeated surgeries under anesthesia.

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## References

Safety of active surveillance program for recurrent nonmuscle-invasive bladder carcinoma. "Patients with recurrent, small (<1 cm), nonmuscle-invasive bladder tumors can be safely offered monitoring under an active surveillance protocol, with a minimal risk of progression in either grade or stage, thus reducing the amount of surgical intervention they might undergo throughout their life." *Urology*. 2009 Jun;73(6):1306-10. Epub 2009 Apr 18. Hernández V, Alvarez M, de la Peña E, Amaruch N, Martín MD, de la Morena JM, Gómez V, Llorente C. Department of Urology, Hospital Universitario Fundación Alcorcón, Madrid, Spain. PMID: 19375783 <http://www.ncbi.nlm.nih.gov/pubmed/19375783>

Active surveillance of low grade bladder tumors. "Recurrent papillary bladder tumors in patients with history of low grade Ta tumor(s) pose minimal risk for the patient. An active surveillance policy, without immediate resection of the tumor may be considered in these cases." *Arch Ital Urol Androl*. 2008 Dec;80(4):132-5. Gofrit ON, Shapiro A. Department of Urology, Hadassah University Medical Center, Jerusalem, Israel PubMed: <http://www.ncbi.nlm.nih.gov/pubmed/19235428>

Conservative management of low risk superficial bladder tumors: "Due to the high rate of recurrence, patients experience the potential risks and morbidity of frequent surgical intervention, despite the often slow growth rate and low risk of progression of such tumors. Recent experiences have suggested that some patients with low grade superficial tumors may be treated expectantly." *J Urol*. 2008 Jan;179(1):87-90; discussion 90. Epub 2007 Nov 12. Pruthi RS, Baldwin N, Bhalani V, Wallen EM. Division of Urologic Surgery, The University of North Carolina at Chapel Hill, Chapel Hill, North Carolina 27599, USA PubMed: <http://www.ncbi.nlm.nih.gov/pubmed/17997444>

Expectant treatment of small, recurrent, low-grade, noninvasive tumors of the urinary bladder - "As long as the tumors are low grade, the risk of invasion or metastasis is zero. Every small papillary tumor does not require removal when observed. Some of these tumors grow very slowly and, with proper reassurance, can be safely monitored." Jan-Feb.2006 Mark Soloway; Miami; *Urologic Oncology: Seminars and Original Investigations* Volume 24, Issue 1 PubMed

Watchful Waiting Policy in Recurrent Ta G1 Bladder Tumors &ldquo;Small, recurrent papillary bladder tumors after resection of low-grade Ta tumor(s) pose minimal risk for the patient. A watchful waiting policy&mdash; without resection of the tumor&mdash;may be considered in these patients.&rdquo; European Urology February 2006 Ofer N. Gofrit, et al. Israel; Volume 49, Issue 2 Pages 303-307 PubMed

Expectant management of small, recurrent, noninvasive papillary bladder tumors. &ldquo;Small, recurrent, low grade appearing bladder tumors are slow growing and pose minimal risk. Therefore, as an alternative to in office fulguration to minimize morbidity and cost associated with repeat transurethral resection it may not be necessary to remove these tumors promptly at new tumor occurrence or recurrence.J Urol. 2003 Aug; Soloway MS, Bruck DS, Kim SS. Department of Urology, University of Miami, Florida 33101, USA. 170(2 Pt 1):438-41 PMID: 12853794

Chemoresection for superficial bladder cancer &ldquo;Chemical resection of tumors can be cheaper and more comfortable for the patient than TUR, avoiding hospitalization, anesthesia and surgery. It can prolong the disease free interval. Low risk tumors are often treated too aggressively, routine TUR for recurrences is riskier than appreciated. The risk of leaving a marker lesion has been shown to be 0% for low risk, 2% for intermediate risk, and 7%for high risk.&rdquo;&rdquo; 2003, conference presentation, W.Oosterlinck, MD, PhD, Ghent University Hospital, Belgium; Member of EORTC, EUA <http://blcwebcafe.org/content/view/148/159/lang,english/#chemoresection>

Phase II trials in Ta, T1 bladder cancer. The marker tumour concept. Br J Urol. 1996 May van der Meijden AP, Hall RR, Kurth KH, Bouffieux C, Sylvester R.Bosch Medical Center, 's Hertogenbosch, Netherlands,;77(5):634-7.PMID: 8689102

The use of the marker tumor concept in Ta, T1 bladder cancer: is it justified? &ldquo;Data from six trials indicate the the risk of leaving an invasive tumor behind or that a tumor might progress while being treated with instillations is 0.8% (3/383).&rdquo; Urol Oncol. 2002 Jan-Feb;7(1):31-3. van der Meijden AP. PubMed: <http://www.ncbi.nlm.nih.gov/pubmed/12474538>

2010 Guidelines on TaT1 (Non-muscle invasive) Bladder Cancer &ldquo;Because of the risk of recurrence and progression, patients with TaT1 bladder tumours need be followed; however, the frequency and duration of cystoscopies should reflect the individual patient&rsquo;s degree of risk. Using risk tables\* we are able to predict the short-term and long-term risks of both recurrence and progression in individual patients and can adapt the follow-up schedule accordingly.&rdquo; 2010 EUA; Guidelines <http://www.uroweb.org/?id=218&gid=1> M. Babjuk, W. Oosterlinck, R. Sylvester, E. Kaasinen, A. Böhle, J. Palou, M. Rouprêt© European Association of Urology 2010. FOLLOW-UP OF PATIENTS WITH TaT1 BLADDER TUMOURS:

\* Predicting recurrence and progression in individual patients with stage Ta T1 bladder cancer using EORTC risk tables: a combined analysis of 2596 patients from seven EORTC trials. Eur Urol 2006 Mar;49(3):466-75; discussion 475-7. Sylvester RJ, et al; EORTC Data Center, Brussels, Belgium. <http://www.eortc.be/tools/bladdercalculator> Risk calculator

WebCafe: 2006: New data support 'watchful waiting' instead of automatic removal of low grade, Ta non-invasive bladder tumors, see, "Observation of Ta,grade 1 bladder tumors, Acceptable?" <http://blcwebcafe.org/content/view/148/159/lang,english/#observation>

WebCafe: Chemo-resection, 2003, presentation by W.Oosterlinck, MD, PhD, Ghent University Hospital, Belgium; Member of EORTC, EUA <http://blcwebcafe.org/content/view/148/159/lang,english/#chemoresection>

