

A faint, stylized silhouette of a human figure is visible in the background, overlaid on a dark blue gradient. The silhouette is composed of light blue lines and shapes, showing the head, torso, and limbs.

Pascal Rischmann

BCG is known to be an efficient for treating intermediate- to high-risk superficial bladder cancer (4).

BCG-treatment causes problems related to side-effects (5):

Systemic complications are rare but local symptoms like pain, burning, pollakiuria and hematuria are still very frequent (60%-80%).

These reactions are, on the one hand, certain proof for the efficacy, but, on the other hand, might also be reason for a lower compliance of patients to BCG-therapy (4, 6).

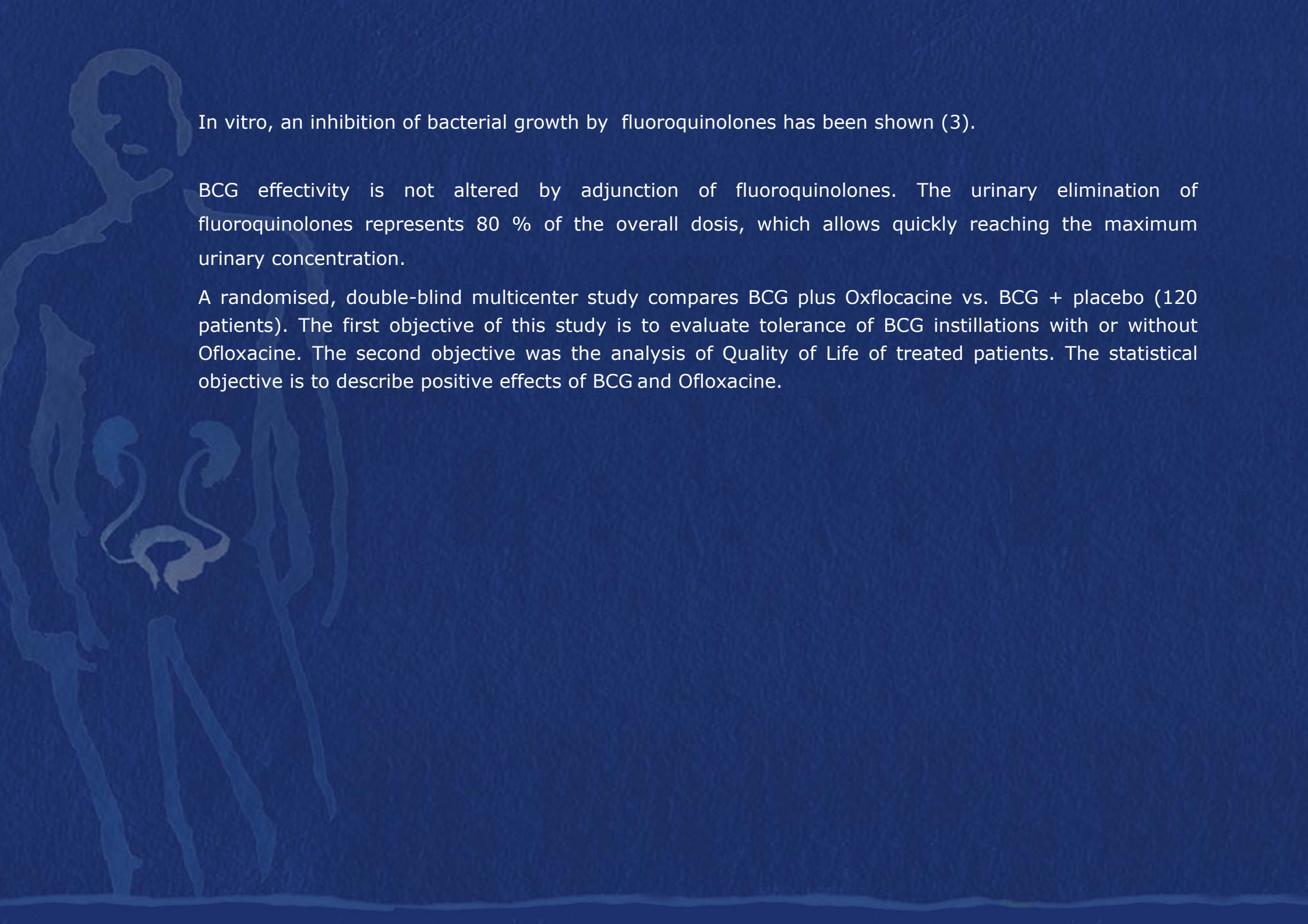
Numerous approaches exist for improving tolerance of treatment :

For one part, modification of the treatment regimen (in terms of chronology) or dose reduction down to 30% in induction therapy and two-thirds in maintenance therapy (2,4).

For the other part the associated use of an anti-tuberculosis drug might help in obtaining an efficient urine-concentration (1).

This is the reason, why other treatment regimens are being studied, especially the essay ITB01 (see PowerPoint presentation).

The starting-hypothesis is, that the local inflammatory response might be controllable by limiting the contact time of BCG in the bladder.



In vitro, an inhibition of bacterial growth by fluoroquinolones has been shown (3).

BCG effectivity is not altered by adjunction of fluoroquinolones. The urinary elimination of fluoroquinolones represents 80 % of the overall dosis, which allows quickly reaching the maximum urinary concentration.

A randomised, double-blind multicenter study compares BCG plus Oxfloracine vs. BCG + placebo (120 patients). The first objective of this study is to evaluate tolerance of BCG instillations with or without Ofloxacin. The second objective was the analysis of Quality of Life of treated patients. The statistical objective is to describe positive effects of BCG and Ofloxacin.



References:

- 1 - Al Khalifa M et al : The effect of isoniazid on BCG-induced toxicity in patients with superficial bladder cancer. Eur Urol.;37 S 1:26-30 (2000).
- 2 - Bassi P et al : Modified induction course: a solution to side effects. Eur. Urol; :37 S 1 31-2 (2000)
- 3 - Durek C.: Interference of modern antibiotics with bacillus Calmette et Guérin viability J.Urol. 162, 1959 -1962 (2000)
- 4 - Lamm D.L. et al : Maintenance bacillus Calmette et Guérin immunotherapy for recurrent TA T1 and carcinoma in situ transitional cell carcinoma of the bladder : a randomised Southwest oncology group study J. Urol ;163: 1124-1129 (2000)
- 5 - Lamm DL : Complications of Bacillus Calmette et Guérin immunotherapy. Urol. Clin; N. Am;19 (3) 565-572 (1992)
- 6 - Saint F et al :.Leukocyturia as a predictor of tolerance and efficacy of intravesical BCG maintenance therapy for superficial bladder cancer.Urology. Apr;57(4):617-21 (2001)