# Regional Lymphotropic Therapy in Patients with Acute Paraproctitis

Alexey Leonidovich Charyshkin and Ivan Nikolaevich Dementyev

Hospital Surgery Department, Ulyanovsk State University, ul. L. Tolstogo 42, Ulyanovsk, 432970 Russia
charyshkin_a@ mail.ru

**Abstract:** The study focused on improving the results of surgical treatment in patients with acute paraproctitis using the elaborated method of regional lymphotropic therapy was carried out. The elaborated method of regional lymphotropic therapy for patients with acute paraproctitis is described in this work (application for an invention № 2 013 103 966). Design included the combined retrospective, prospective, and exploratory studies. The results of examination and treatment of 190 patients diagnosed with acute paraproctitis during the period of 2005–2012 are presented. The distribution of patients with respect to the type of pathological process was as follows: perianal submucous paraproctitis was diagnosed in 119 patients (62.6%); ischiorectal paraproctitis, in 68 patients (35.8%); and pelviorectal paraproctitis, in 3 patients (1.6%). In most cases, the disease was observed among able-bodied population aged 21–50 (median age of the patients in the examined group was 40.2±8.4 years for males and 37.7±9.3 years for females). The results of immunological examination have shown that acute paraproctitis disturbs all the components of the immune system; that is why the therapy for this disease needs to be optimized by including immunomodulator Derinat in the regional lymphotropic therapy. The patients were divided into 3 groups depending on the type of therapy used during the postoperative period. An evaluation of the method proposed for regional lymphotropic therapy in patients with acute paraproctitis was carried out. The method proposed for regional lymphotropic therapy in patients with acute paraproctitis allows one to reduce the number of disease recurrences and normalizes the immune protection.
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**Keywords:** acute paraproctitis, regional lymphotropic therapy, Derinat, T-cell-mediated immunity, humoral immunity, postsurgical complications.

## 1. Introduction

Impairment of local and humoral immunity is one of the key factors causing the emergence of severe forms of acute paraproctitis [1,2,3].

A significant potential of positive results of using the methods and facilities of clinical lymphology in various fields of medicine has been accumulated [4,5]. Regional lymphotropic therapy ensuring high and long-term concentrations of drugs in the pathological focus and regional lymph nodes is the most efficient and simple method for delivering pharmacological agents to the lymphatic system [6,7].

Many researchers have mentioned that the indirect endolymphatic introduction of antibacterial drugs has reliable advantages over intravenous and intramuscular drug delivery methods [8,9].

Our study was aimed at improving the results of surgical treatment in patients with acute paraproctitis by using regional lymphotropic therapy.

## 2. Material and Methods

The results of examination and treatment of 190 patients diagnosed with acute paraproctitis receiving inpatient care at the Ulyanovsk Central City Clinical Hospital over the period of 2005–2012.

Design: combined retrospective, prospective, and exploratory study. The period of study: 2005–2012. A total of 249 patients were selected at the primary stage. The number of patients included in the analysis was 190.

The criteria for including patients in the study were as follows: age of 18 years and older; both male and female sex; diagnosed acute paraproctitis.

Exclusion criteria: age under 18 years; chronic paraproctitis; myocardial infarction; acute disturbances of cerebral circulation.

The distribution of patients over the type of pathological process was as follows: subcutaneous-submucosal paraproctitis was diagnosed in 119 (62.6 %) patients; ischiorectal paraproctitis, in 68 (35.8 %) patients; pelviorectal paraproctitis, in 3 (1.6 %).

The age and sex structure of patients with acute paraproctitis in the cohort under study is shown below (Table 1).

It is clear from the analysis of the data in Table 1 that male patients predominate statistically reliably ($p<0.05$) among the patients, while females make 20 %. In most cases, the disease occurs among

the able-bodied individuals aged 21–50 (the mean age of patients in the group under study: 40.2±8.4 for men and 37.7±9.3 for women).

Table 1. Age and sex structure of the cohort under study

| Ages, years | Males | | Females | |
|---|---|---|---|---|
| | Number of patients | % | Number of patients | % |
| 18-20 | 4 | 2.1 | 1 | 0.5 |
| 21-30 | 22 | 11.6 | 8 | 4.2 |
| 31-40 | 21 | 11.1 | 13 | 6.9 |
| 41-50 | 53 | 27.9 | 12 | 6.3 |
| 51-60 | 39 | 20.5 | 3 | 1.6 |
| 61 and older | 13 | 6.8 | 1 | 0.5 |
| Total | 152 | 80 | 38 | 20 |

Clinico-laboratory, bacteriological, immunological, roentgenologic, endoscopic, and statistic methods were employed to solve the problem assigned.

Compete blood count test was performed in a clinical laboratory; the leukocyte intoxication index (LII) was determined using Ostrovsky formula.

All the patients were operated within the first day after being admitted to hospital. The following procedures were performed to the patients under intravenous anaesthesia: opening of the suppurative focus; removal of necrotic and devitalized tissues, pus and sequestrum; destruction of the existing intersection; dissection of the sinus tract; and excision of a crypt. The cavity was washed with an antiseptic solution (0.05% aqueous chlorohexidine solution).

The patients were divided into 3 groups depending on the therapy type used during the postoperative period. No significant differences in sex, age, and type of concomitant pathologies were observed between the groups.

Group 1 (control) consisted of 131 patients who received basic treatment. Topical treatment of wounds was carried out in accordance with the phases of the wound healing process. Bandages with anti-infective agents (chlorhexidine, hydrogen peroxide, iodopiron) and hydrophylic ointments (levomecol) were applied daily during the inflammation phase. Water-soluble and oil-based ointments, as well as stimulating agents, were applied during the regeneration phase. Stimulating ointments were used during the epitheliazation and maturation phases. The patients received analgesic agents (Ketorolak) and antibacterial therapy (Cefotaxime).

Group 2 (control) consisted of 15 patients who received basic treatment similar to that in group 1: analgesic agents (Ketorolac), antibacterial therapy (Cefotaxime), and additionally subcutaneously received Derinat solution (2 ml, repeated four times every two days) in the shoulder region.

Group 3 (test group) consisted of 44 patients who received basic treatment and drugs that were injected subcutaneously, on the boundary between the middle and lower shin during the postoperative period according to the procedure designed (application for an invention № 2 013 103 966). Preparation lidase (32 U) diluted with 2 ml of 0.25% novocaine was injected, followed by administration (after 5–10 min) of 1000 mg of third-generation cephalosporin (Cefotaxime) diluted in 5 ml of 0.25% novocaine once a day during 5 days and 5 ml of Derinat solution four times every two days. Informed voluntary consent for medical procedures was obtained from all the patients. The comparative analysis of the results was carried out based on the clinical data, laboratory data, and microbiological studies.

According to the conclusion of the Ethics Committee (School of Medicine, Ecology, and Physical Education, Ulyanovsk State University) regarding the use of the designed method of regional lymphotropic therapy in patients with acute paraproctitis, the expected efficiency and safety are scientifically justified. The studies were carried out in accordance with the ethical norms accepted in the Declaration of Helsinki (1964). An informed voluntary consent for medical interventions was obtained from all the patients.

**3. Results**

The immune status was studied in 55 patients (20 patients from the test group; 20 patients from Group 1, and 15 patients from Group 2). Table 2 shows the results of studying T cell-mediated immunity in patients with acute paraproctitis prior to the treatment. When comparing the results of studying the T cell-mediated immunity in patients with acute paraproctitis prior to the treatment with those obtained in healthy individuals, one can see that the absolute number of lymphocytes, T cells (CD3+), T helper cells (CD4+) in peripheral blood in patients with acute paraproctitis was below the norm. The ratio between T-helper and suppressor cells (CD4+/CD8+) was also lower than that in healthy volunteers.

The contents of immunoglobulins M and A in blood plasma did not reliably differ from those in healthy volunteers. Table 3 presents the characteristics of disruptions in the humoral immunity in patients with acute paraproctitis.

The following changes have been revealed in the humoral immunity (Table 3). The amount of CD20+ (B lymphocytes) increased to 0.29±0.02 abs.$\times 10^9$/l in Group 1, to 0.28±0.04 abs.$\times 10^9$/l in

Group 2, and 0.31±0.03 abs.×$10^9$/l in Group 3 as compared to healthy volunteers (0.19 ±0.03 ($p<0.05$)). The IgG level increased to 15.64±0.37 g/l in group 1, to 15.43±0.31 g/l in group 2, and to 15.37±0.28 g/l in group 3 as compared to that in healthy volunteers (10.87±0.41 ($p < 0.05$). The CIC level was 110.3±5.13, 113.4±4.01, and 114.1±3.28 cond. units in group 1, group 2, and group 3, respectively, which is reliably higher than that in healthy volunteers (51.27±1.93 ($p<0.05$)).

**Table 2**. Results of studying the T cell-mediated immunity in patients with acute paraproctitis prior to treatment

| Indices (units) | Normal value | Healthy volunteers (n=20) | Group 1 (n = 20) | Group 2 (n = 15) | Group 3 (n = 20) |
|---|---|---|---|---|---|
| Lymphocytes (abs.×$10^9$/l) | 1.6-3.35 | 1.89±0.03 | 1.73±0.02* | 1.69±0.02* | 1.68±0.03* |
| CD3+ (abs.×$10^9$/l) | 0.7-2.25 | 1.23±0.05 | 0.96±0.03* | 0.95±0.05* | 0.94±0.04* |
| CD4+ (abs.×$10^9$/l) | 0.55-1.55 | 0.87±0.11 | 0.58±0.03* | 0.60±0.04* | 0.63±0.02* |
| CD8+ (abs.×$10^9$/l) | 0.25-0.75 | 0.39±0.04 | 0.41±0.02* | 0.40±0.05* | 0.40±0.03* |
| CD4+/CD8+ (abs.) | 1.5-3 | 2.29±0.03 | 1.46±0.04* | 1.49±0.04* | 1.52±0.03* |

Note: * – reliability of the results as compared to the normal indices at $p<0.05$.

**Table 3.** Results of studying the humoral immunity in patients with acute paraproctitis prior to treatment

| Indices (units) | Normal value | Healthy volunteers (n=20) | Group 1 (n = 20) | Group 2 (n = 15) | Group 3 (n = 20) |
|---|---|---|---|---|---|
| CD20+ (abs.×$10^9$/l) | 0.15-0.5 | 0.19 ±0.03 | 0.29±0.02* | 0.28±0.04* | 0.31±0.03* |
| IgA(g/l) | 1.6-3.0 | 1.93 ±0.04 | 1.91±0.05 | 1.90±0.04 | 1.92±0.03 |
| IgG (g/l) | 7.0-20.0 | 10.87±0.41 | 15.64±0.37* | 15.43±0.31* | 15.37±0.28* |
| IgM (g/l) | 0.5-2.0 | 1.11±0.02 | 1.08±0.07 | 1.07±0.06 | 1.09±0.05 |
| CIC (cond. units.) | <90 | 51.27±1.93 | 110.3±5.13* | 113.4±4.01* | 114.1±3.28* |

Note: * – reliability of the results as compared to the normal indices at $p < 0.05$.

Thus, the results of immunological examination have demonstrated that all the immunity components are disturbed in patients with acute paraproctitis; hence, the treatment for this disorder needs to be optimized by including immunomodulator Derinat in the regional lymphotropic therapy.

LII was analyzed in the patients under study. In groups 1, 2, and 3 (Table 4), LII value was 7.8±0.3, 6.1±0.1, and 5.6±0.2, respectively, which is significantly lower than that in the control group ($p<0.05$). On day 5, LII in group 3 was lower than that in patients in groups 1 and 2, while on day 10 this index was within the normal value in all the groups.

**Table 4**. Dynamics of LII during the postoperative period. Note: *,** – reliable intergroup differences ($p<0.05$).

| Patient groups, n=190 | LII after the surgery | | |
|---|---|---|---|
| | 2 days | 5 days | 10 days |
| Group 1, n=131 | 7.8±0.3 | 6.3±0.3 | 2.2±0.2 |
| Group 2, n=15 | 6.1±0.1* | 5.0±0.2* | 2.3±0.2 |
| Group 3, n=44 | 5.6±0.2** | 4.2±0.1** | 2.1±0.1 |

A statistically significant lower content of mean molecular weight peptides as compared to those in groups 1 and 2 was observed in group 3. These differences can be seen during the entire postoperative period.

The indices of the average molecules in group 3 normalize by day 5, while in groups 1 and 2 it occurs only by day 10 (Table 5).

**Table 5.** Dynamics of the content of mean molecular weight molecules in blood serum (opt. units). Note: *,** – reliable intergroup differences ($p<0.05$).

| Treatment type | day 2 | day 5 | day 10 |
|---|---|---|---|
| Group 1 | 0.51±0.01 | 0.39± 0.02 | 0.25±0.01 |
| Group 2 | 0.49±0.03* | 0.30±0.01* | 0.23±0.02 |
| Group 3 | 0.41±0.02** | 0.24±0.02** | 0.22±0.01 |

The average duration of soft tissue infiltration in groups 1, 2, and 3 was 6.2±1.4, 5.0±1.3, and 4.3±1.6 days, respectively. The difference in duration is statistically significant ($p<0.05$).

An analysis of the data regarding the terms of wound cleansing among the groups under study has demonstrated that wound cleansing in group 1, where patients received the conventional treatment during the postoperative period, occurred only on day 7.5±1.4. In group 2, the elimination of necrotic suppurative discharge occurred on day 5.0±1.5. The best results were achieved in group 3 patients (4.2±1.8 days ($p<0.05$)).

Granulation and epithelization of wound edges in groups 1, 2, and 3 were observed on days 9.5±1.3; 7.6±1.2; and 6.1±1.1, attesting to the better pronounced clinical effect when using the proposed method of regional lymphotropic therapy ($p<0.05$).

Thus, it can be seen from the data obtained that the best results are observed in patient group 3, where the elimination of infiltration, wound cleansing, and the emergence of granulations and epithelization is observed at early terms, which reduces the wound healing period.

The structure of early postoperative complications in groups of patients was as follows: 16% (21 patients) in group 1; 20% (3 patients) in group 2; and 9.1 % (4 patients) in group 3. The

difference between these indices is statistically significant ($p<0.05$).

The structure of early postoperative complications is shown in Table 6.

**Table 6.** Structure of early postoperative complications

| Index | Group 1 n=131 | Group 2 n=15 | Group 3 n=44 |
|---|---|---|---|
| Frequency of complications (total) | 16% (n=21) | 20% (n=3) | 9.1% (n=4) |
| An increase in suppurative area | 7.6% (n=10) | 6.6% (n=1) | – |
| Hemorrhage | 5.3% (n=7) | 13.3% (n=2) | 4.5% (n=2) |
| Urinary retention | 3% (n=4) | – | 4.5% (n=2) |

The most frequent cause of early postoperative complications was associated with increased suppurative area; this complication was not observed in group 3. Hemorrhage was observed in 5.3; 13.3; and 4.5 % of group 1, 2, 3 patients, respectively. Urinary retention emerged in 3 % of group 1 patients and 4.5 % of group 3 patients. This complication was not observed in group 2 patients and is associated with the concomitant pathology of prostate gland. When examining these data, one can see that the maximum number of early postoperative complications is observed in group 1, while the minimum number is observed in group 3 of patients.

The average duration of hospital admission was 9.2±6.0 days for group 1; 8.1±2.7 days for group 2; and 6.3±3.2 days for group 3, which is on average 3 days shorter than for group 1 ($p<0.05$).

The immunological study prior to and after the treatment was carried out in 20 group 1 patients. After the conventional treatment (Table 7), a further decrease in the amount of lymphocytes (1.64±0.03 abs.$\times10^9$/l), CD3+ (T lymphocytes) (0.89±0.04 abs.$\times10^9$/l), CD4+ (T helper cells) (0.53±0.02 abs.$\times10^9$/l), and the load index (1.32±0.03) was observed in group 1 patients.

**Table 7.** Results of studying the T-cell-mediated immunity in patients with acute paraproctitis in group 1 after the therapy

| Indices (units) | Normal value | Healthy volunteers (n=20) | Group 1 prior to the treatment (n=20) | Group 1 after the treatment (n=20) |
|---|---|---|---|---|
| Lymphocytes (abs.$\times10^9$/l) | 1.6-3.35 | 1.89±0.03 | 1.73±0.02 | 1.64±0.03* |
| CD3+ (abs.$\times10^9$/l) | 0.7-2.25 | 1.23±0.05 | 0.96±0.03 | 0.89±0.04* |
| CD4+ (abs.$\times10^9$/l) | 0.55-1.55 | 0.87±0.11 | 0.58±0.03 | 0.53±0.02* |
| CD8+ (abs.$\times10^9$/l) | 0.25-0.75 | 0.39±0.04 | 0.41±0.02 | 0.42±0.03 |
| CD4+/CD8+ (abs.) | 1.5-3 | 2.29±0.03 | 1.46±0.04* | 1.32±0.03* |

Note: * – reliability of the results as compared to the indices prior to the treatment at $p < 0.05$.

A decrease in the level of CD20+ (B lymphocytes) to 0.26±0.03 abs.$\times10^9$/l and an increase in IgG level to 16.17±0.18 g/l were observed in the humoral immunity (Table 8) in group 1 patients after the treatment. The CIC level decreased significantly, but still remained higher than that in healthy volunteers (91.3±2.19 cond. units).

**Table 8.** Results of studying the humoral immunity in patients with acute paraproctitis in group 1 after the therapy

| Indices (units) | Normal value | Healthy volunteers (n=20) | Group 1 prior to the treatment (n=20) | Group 1 after the treatment (n=20) |
|---|---|---|---|---|
| CD20+ (abs.$\times10^9$/l) | 0.15-0.5 | 0.19 ±0.03 | 0.29±0.02 | 0.26±0.03* |
| IgA(g/l) | 1.6-3.0 | 1.93 ±0.04 | 1.91±0.05 | 1.89±0.03 |
| IgG (g/l) | 7.0-20.0 | 10.87±0.41 | 15.64±0.37 | 16.17±0.18* |
| IgM (g/l) | 0.5-2.0 | 1.11±0.02 | 1.08±0.07 | 1.10±0.05 |
| CIC (cond. units.) | <90 | 51.27±1.93 | 110.3±5.13 | 91.3±2.19* |

Note: * – reliability of the results as compared to the indices prior to the treatment at $p < 0.05$.

A reliable increase in the levels of lymphocytes (1.71±0.03 abs.$\times10^9$/l), CD3+ (T lymphocytes) (1.01±0.06 abs.$\times10^9$/l), CD4+ (T helper cells) (0.64±0.04 abs.$\times10^9$/l) was observed in group 2 patients (Table 9). The load index (CD4+/CD8+) normalized (1.59±0.03), which attest to normalization of the ratios between T lymphocyte subpopulations (T-helper and T-suppressor cells).

**Table 9.** Results of studying the T-cell-mediated immunity in patients with acute paraproctitis in group 2 after the treatment

| Indices (units) | Normal value | Healthy volunteers (n=20) | Group 2 prior to the treatment (n=15) | Group 2 after the treatment (n=15) |
|---|---|---|---|---|
| Lymphocytes (abs.×$10^9$/l) | 1.6-3.35 | 1.89±0.03 | 1.69±0.02 | 1.71±0.03* |
| CD3+ (abs.×$10^9$/l) | 0.7-2.25 | 1.23±0.05 | 0.95±0.05 | 1.01±0.06* |
| CD4+ (abs.×$10^9$/l) | 0.55-1.55 | 0.87±0.11 | 0.60±0.04 | 0.64±0.04* |
| CD8+ (abs.×$10^9$/l) | 0.25-0.75 | 0.39±0.04 | 0.40±0.05 | 0.41±0.05 |
| CD4+/CD8+ (abs.) | 1.5-3 | 2.29±0.03 | 1.49±0.04 | 1.59±0.03* |

Note: * – reliability of the results as compared to the indices prior to the treatment at $p < 0.05$.

**Table 10.** Results of studying the humoral immunity in patients with acute paraproctitis in group 2 after the treatment

| Indices (units) | Normal value | Healthy volunteers (n=20) | Group 2 prior to the treatment (n=15) | Group 2 after the treatment (n=15) |
|---|---|---|---|---|
| CD20+ abs.×$10^9$/l) | 0.15-0.5 | 0.19 ±0.03 | 0.28±0.04 | 0.28±0.02 |
| IgA (g/l) | 1.6-3.0 | 1.93 ±0.04 | 1.90±0.04 | 1.91±0.03 |
| IgG (g/l) | 7.0-20.0 | 10.87±0.41 | 15.43±0.31 | 14.34±0.28* |
| IgM (g/l) | 0.5-2.0 | 1.11±0.02 | 1.07±0.06 | 1.07±0.04 |
| CIC (cond. units.) | <90 | 51.27±1.93 | 113.4±4.01 | 84.5±2.31* |

Note: * – reliability of the results as compared to the indices prior to the treatment at $p < 0.05$.

No decrease in the level of CD20+ (B lymphocytes) was observed for the humoral immunity (Table 10) in group 2 patients after the treatment (0.28±0.02 abs.×$10^9$/l); IgG level decreased to 14.34±0.28 g/l. The CIC level decreased to 84.5±2.31 cond. units, which corresponds to the normal value.

The levels of lymphocytes (1.79±0.02 abs.×$10^9$/l), CD3+ (T lymphocytes) (1.06±0.05 abs.×$10^9$/l), and CD4+ (T helper cells) (0.67±0.02 abs.×$10^9$/l) reliably increased in group 3 patients (Table 11). The load index (CD4+/CD8+) normalized (1.63±0.02), which attests to the fact that the ratios between T-lymphocyte subpopulations (T-helper and T-suppressor cells) was also normalized.

**Table 11**. Results of studying the T-cell-mediated immunity in patients with acute paraproctitis in group 3 after the treatment

| Indices (units) | Normal value | Healthy volunteers (n=20) | Group 3 prior to the treatment (n=20) | Group 3 prior after the treatment (n=20) |
|---|---|---|---|---|
| Lymphocytes (abs.×$10^9$/l) | 1.6-3.35 | 1.89±0.03 | 1.68±0.03 | 1.79±0.02* |
| CD3+ (abs.×$10^9$/l) | 0.7-2.25 | 1.23±0.05 | 0.94±0.04 | 1.06±0.05* |
| CD4+ (abs.×$10^9$/l) | 0.55-1.55 | 0.87±0.11 | 0.63±0.02 | 0.67±0.02* |
| CD8+ (abs.×$10^9$/l) | 0.25-0.75 | 0.39±0.04 | 0.40±0.03 | 0.41±0.05 |
| CD4+/CD8+ (abs.) | 1.5-3 | 2.29±0.03 | 1.52±0.03 | 1.63±0.02* |

Note: * – reliability of the results as compared to the indices prior to the treatment at $p < 0.05$.

A decrease in the level of CD20+ (B lymphocytes) to 0.27±0.03 abs.×$10^9$/l and a decrease in IgG level to 14.12±0.31 g/l were observed in the humoral immunity of group 3 patients after the treatment (Table 12). The CIC level significantly decreased to 76.2±3.22 cond. units, which corresponds to the normal values.

**Table 12.** Results of studying the humoral immunity in group 3 patients with acute paraproctitis after the treatment

| Indices (units) | Normal value | Healthy volunteers (n=20) | Group 3 prior to the treatment (n=20) | Group 3 after the treatment (n=20) |
|---|---|---|---|---|
| CD20+ (abs.×$10^9$/l) | 0.15-0.5 | 0.19 ±0.03 | 0.31±0.03 | 0.27±0.03* |
| IgA(g/l) | 1.6-3.0 | 1.93 ±0.04 | 1.92±0.03 | 1.91±0.03 |
| IgG (g/l) | 7.0-20.0 | 10.87±0.41 | 15.37±0.28 | 14.12±0.31* |
| IgM (g/l) | 0.5-2.0 | 1.11±0.02 | 1.09±0.05 | 1.07±0.04 |
| CIC (cond. units) | <90 | 51.27±1.93 | 114.1±3.28 | 76.2±3.22* |

Note: * – reliability of the results as compared to the indices prior to the treatment at $p < 0.05$.

Thus, the results of immunological studies have demonstrated that further suppression of immunological activities takes place in group 1 patients. In group 2 patients with acute paraproctitis, the immune protection indices were normalized due to the use of Derinat during postoperative therapy. However, the greatest statistically significant effect was detected in group 3 patients after Derinat was included in lymphotropic therapy.

The improvement of treatment outcomes in patients with acute paraproctitis is associated with high efficacy of the proposed lymphotropic therapy [10], which makes it possible to reduce the number of disease recurrences and ensures the normalization of the immune protection.

**Corresponding Author:**
Dr. A.L. Charyshkin
Hospital Surgery Department
Ulyanovsk State University, ul. L. Tolstogo 42,
Ulyanovsk, 432970 Russia
charyshkin_a@ mail.ru

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